IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK Hon. Robert Kugler **Plaintiffs' Memorandum of Law in Support of Their Motion for Class Certification of Consumer Economic Loss Claims**

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR CLASS CERTIFICATION OF CONSUMER ECONOMIC LOSS CLAIMS

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Other Authorities

COME NOW, Consumer Economic Loss ("EL") Plaintiffs Asha Lamy, Sandra Kelly, Evelyn Rice, Jay Meader, Mark Hays, Charlie Johnston, Merilyn Andre, Peter O'Brien, Ron Molinaro, Estate of Elenora Deutenberg, Lubertha Powell, Lawrence Edwards, Marlin Anderson, Georgia Fatigato, Leland Gildner, Brian Wineinger, Raleigh Wolfe, Joseph Kessinger, Glenda Cooper, Sandy Bell, Talsie Neal, Linda Crocker, Veronica Longwell, Jennifer Johnson, Flora McGilvery, Marzanna Glab, Antoinette Sims, James Lawson, James Childs, Radhakrishna Shetty, Billy Joe Bruner, Alphonse Borkowski, Joseph Cacaccio, John Duffy, Gerald Nelson, Gary Burnett, Miranda Dudley, Dennis Kaplan, Lawrence Semmel, Eric Erwin, Jynona Gail Lee, Brittney Means, Samuel Cisneros, Cheryl Mullins, Robin Roberts, Mary McLean, (hereinafter, "Plaintiffs"), who file this Memorandum of Law in Support of their Motion for Class Certification pursuant to Fed. R. Civ. P. 23(a), (b)(3), and (g).

I. INTRODUCTION

This multidistrict litigation ("MDL") arises out of one of the largest class I prescription pharmaceutical recalls in United States history, due to contamination of valsartan[1] blood pressure medications with extremely potent human carcinogens, N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA"). The contamination was the direct result of the Defendants' gross violations of state law and parallel federal regulations, including those regarding good manufacturing practices ("cGMPs").

Plaintiffs have asserted claims against numerous Active Pharmaceutical Ingredient ("API") Manufacturers, Finished Dose ("FD") Manufacturers, three Wholesalers Defendants, and eight Retail Pharmacy Defendants for economic losses and medical monitoring. In addition to these

[1] Valsartan and Valsartan Containing Drugs ("VCDs") are the generic versions of the reference listed drugs ("RLDs") DIOVAN® and/or EXFORGE®, which were the brand names.

economic loss and medical monitoring class cases, there are also nearly one thousand (1,000) personal injury cases consolidated before this Court.

This Memorandum of Law supports Plaintiffs' Motion for Class Certification of Consumer Economic Loss Claims, wherein Consumer Economic Loss Plaintiffs seek Rule 23(b)(3) certification of numerous end-user/consumer economic loss classes and sub-classes against Manufacturers, Wholesaler Defendants, and Retail Pharmacy Defendants.[2] These consumer classes are predicated on several state law claims including: (1) express warranty claims against the Manufacturers; (2) implied warranty claims against the Manufacturers and Retail Pharmacy Defendants; (3) common law fraud claims against the Manufacturers; (4) consumer protection act claims against Manufacturers and Retail Pharmacy Defendants; and (5) unjust enrichment claims against the Wholesaler Defendants, and Retailer Pharmacy Defendants.

The Consumer EL Class Plaintiffs and absent Class Members ("Consumer EL Class Members") satisfy all requirements of Fed. R. Civ. P. 23(a) and (b)(3). The trial(s) in this case will use common evidence to establish all elements of Defendants' liability pursuant to these claims at all levels of the chain of distribution. *See* Expert Declaration of John L. Quick (hereafter "Quick Decl."), and Expert Declaration of Dr. Ron Najafi, Ph.D. (hereafter "Najafi Decl."). The common evidence will show that due to the actions/inaction of each group of Defendant in this case, the Defendants illegally distributed, sold, and/or dispensed economically worthless VCDs to the consumer economic loss plaintiffs. *See* Expert Declaration of Professor Rena Conti, Ph.D. (hereafter "Conti Decl."). The Consumer EL Class Members' purchases of these economically worthless, illegally dispensed, adulterated and misbranded VCDs amounted to breaches of

[2] Separate but consistent Memoranda are being filed by the Third Party Payor ("TPP") and Medical Monitoring plaintiffs.

warranty, fraud, and violations of consumer protection acts by the Manufacturer Defendants and Retail Pharmacy Defendants, which caused Consumer El Class Members' economic injuries. The common evidence will also show that the Wholesaler and Retail Pharmacy Defendants were unjustly enriched as a result of selling these economically worthless VCDs to the Consumer EL Class Members. Defendants' misconduct affected all Consumer EL Class Members in a similar manner.

Additionally, class membership is ascertainable based on objective criteria, and a class trial will present no significant manageability issues, *See* Expert Declaration of Laura Craft (hereafter "Craft Decl."). In fact, a class trial represents the only practical way to efficiently adjudicate the claims here on behalf of the millions of Consumer EL Class Members who are members of one or more Consumer EL Classes (whose class and sub-class membership is determined from common records) who paid in whole or in part for the economically worthless VCDs, which were illegally distributed, sold, and/or dispensed, by Manufacturer Defendants, Wholesaler, and/or Retail Pharmacy Defendants.

The Court should grant Plaintiffs' Motion and certify the Consumer EL Classes set forth in the Class Definitions Table,[3] based on state groupings set forth in the accompanying State Groupings and Legal Authorities Tables,[4] which is discussed in more detail in the body of this Motion *infra*.

II. RELEVANT PROCEDURAL HISTORY OF MDL

On February 14, 2019, the Joint Panel on Multidistrict Litigation (JPML) created this MDL, and assigned it to this Court, to coordinate all actions alleging that "plaintiffs purchased or used generic formulations of valsartan medications containing the nitrosamine impurities NDMA

[3] The Class Definitions Table is attached hereto as **Ex. 1**.
[4] The State Groupings and Legal Authorities Tables are attached hereto as **Ex. 2**.

and/or NDEA."[5] Defendants filed Motions to Dismiss against the then-operative Second Amended Master Economic Loss, Second Amended Master Medical Monitoring, and First Amended Master Personal Injury Complaints.[6] The Court issued a series of thorough opinions that mostly rejected Defendants' various dismissal arguments.[7] Plaintiffs subsequently filed a Motion for Leave to File proposed amended Master Complaints, on which Special Master, Judge Vanaskie, recently issued a Report and Recommendation ("R&R").[8] As contemplated by the scheduling order, Plaintiffs filed the proposed amended Master Complaints conforming to Judge Vanaskie's R&R, and this Motion is filed in accordance therewith.[9]

Extensive document, deposition, and data discovery has been undertaken,[10] which provides significant proof that the elements of Rule 23 are satisfied in connection with the Consumer EL Class claims in the Third Amended Complaint.[11]

III. FACTS RELEVANT TO THIS MOTION

A. Discovery Against the Manufacturer Defendants Has Demonstrated Substantial Manufacturing Defects and Violations of Current Good Manufacturing Practices ("cGMPs") That Were Material to the Pervasive NDMA/NDEA Contamination of Defendants' VCDs

At the outset of this case, counsel for the Defendants represented to the Court that the "case is about the API manufacturing process[,] [c]losely related to that would be the finished dose

[5] *See* D.E. 229, at 2. On December 18, 2019, the JPML expanded the scope of this MDL "to include actions alleging that losartan and irbesartan contain nitrosamine impurities." (D.E. 401, 4.) This Motion pertains only to VCDs.
[6] *See* D.E. 520, 522, 523.
[7] *See* D.E. 675, 728, 775, 818, 838, and 1019 ("the MTD Opinions").
[8] *See* D.E. 1614.
[9] Plaintiffs reserve the right to seek leave to file a corrected or amended Motion for Class Certification to the extent the Court does not adopt the R&R in full.
[10] Discovery is still ongoing, including as to manufacturer ZHP and downstream Defendants, and Plaintiffs reserve all rights accordingly, to the extent such discovery would implicate Rule 23 requirements.
[11] *See* D.E.1708.

manufacturers[,] [b]ut what happened further in the chain is really a sideshow to the main case, which is about the API manufacturers."[12] As shown below in the manufacturer-specific sections,

[redacted] The formation of NDMA/NDEA is a matter of "basic chemistry."[13]

Common evidence[14] will also show that each FD Defendant failed to properly undertake their duties and responsibilities in appropriately confirming the integrity of the manufacturing operations of the API manufacturers (whether vertically integrated or outsourced) when ultimately manufacturing their FD products using that API and introducing these products into the stream of commerce. This resulted in all Manufacturer Defendants' inability to assure that their VCDs were as they represented them to be, *i.e.*, generic versions of DIOVAN and/or EXFORGE and their chemical and therapeutic equivalents.

B. Common Evidence Will Show that Nitrosamines Are Well-Known, Long-Studied Probable Human Carcinogens that Are Formed as a Matter of Basic Chemistry

Common evidence will establish that nitrosamines were commonly understood in the industry and the literature long before the events that gave rise to this litigation. That common evidence will include the Manufacturer Defendants' own admissions. For instance, [redacted]

[12] *See* June 26, 2019 CMC Tr., at 40:7-11.
[13] *See* Najafi Decl. at ¶ 26.
[14] The factual recitations contained in this Memorandum are not meant to present a complete or exhaustive level of detail as to the evidentiary findings after months of discovery. Rather, they present a high-level summary of evidence common to the class regarding the levels and scope of NMDA/NDEA contamination, the most substantial and material cGMP violations, and other facts that are pertinent to this Motion.

[redacted]

Common evidence will also establish that NDMA/NDEA formation is a matter of basic chemistry. That will be proved through expert testimony, published literature, as well as the admissions of the Manufacturer Defendants themselves. As one example, [redacted]

There was also common industry knowledge about how the use of specific solvents might result in the formation of NDMA/NDEA. For example, the DMF solvent that was used by several

[15] **Ex. 3**, Claire Lyons Dep. at 164:1 to 165:13.
[16] **Ex. 4**, Lance Molnar Dep. at 126:14-20.
[17] **Ex. 5**, TEVA-MDL5875-00000603; **Ex. 6**, Raphael Nudelman Dep. at 54:23 to 56:3; **Ex. 7**, PI-Molnar 3 [redacted]
[18] **Ex. 8**, TEVA-MDL2875-00101997 [redacted] **Ex. 9**, TEVA-MDL2875-00101999.
[19] **Ex. 10**, TEVA-MDL2875-00259910; **Ex. 11**, TEVA-MDL2875-00259905.
[20] **Ex. 12**, TEVA-MDL2875-00043320 [redacted]
[21] **Ex. 13**, TEVA-MDL2875-00280442.

Defendants was known to decompose and yield a secondary amine, dimethylamine.[22] And, as detailed below, [redacted]

Common evidence will also be presented that the Manufacturer Defendants' process chemists were aware of the need to avoid manufacturing processes that result in NDMA/NDEA as byproducts. Indeed, a public patent originally filed in November 2013 disclosed a method for manufacturing valsartan API to avoid creating a "nitroso compound."[23] This patent specified *not* to use sodium nitrite to negate the potential for any reaction with nitrous acid, which "can eliminate the generation of impurity."[24] In other words, years prior to the 2018 recalls, this publicly available patent disclosed a production method explicitly designed to avoid the exact mechanism through which NDMA was formed during the valsartan API manufacturing process.[25] [redacted]

[22] **Ex. 14**, ZHP Dep. Ex. 197 (N,N-Dimethylformamide: much more than a solvent, *Tetrahedron 65*, 8313-8323, at 8315); **Ex. 15**, ZHP Dep. Ex. 311 (Armarego, W.L.F., and Perrin, D.D. (1996) *Purification of Laboratory Chemicals*, at 192).
[23] **Ex. 16**, TEVA-MDL2875-00049024 at p.3 of 13.
[24] **Ex. 16**, TEVA-MDL2875-00049024 at p.3 of 13; **Ex. 17**, Anthony Binsol Dep. at 69:15 to 72:24.
[25] **Ex. 16**, TEVA-MDL2875-00049024 at p.3 of 13; **Ex. 17**, Anthony Binsol Dep. At 58:3 to 60:7 ("If you take away the Sodium Nitrite (NaNo2) or Hydrochloric Acid (HCl), you're not going to get the nitrous acid, and then you're not going to get the NDMA").
[26] **Ex. 18**, APL-MDL-2875-2061223 at -232.

1. The ZHP Defendants

a) ZHP's API and Finished Dose Manufacturing

Defendant ZHP is a vertically integrated manufacturer of both valsartan API and FD. ZHP marketed and sold valsartan for sale in the United States, (1) in FD form through its wholly owned subsidiaries Prinston Pharmaceuticals[27] and wholesale distributor Solco Pharmaceuticals,[28] and (2) in API form to Defendant Torrent[29] and Defendant Teva;[30] who then used the ZHP API to manufacture FD for sale in the United States.[31]

b) The ZHP Manufacturing Process Changes

[redacted]

[27] **Ex. 19**, Lijie Wang Dep. at 64:9-12.
[28] **Ex. 20**, Hai Wang Dep. Tr. 191:22-192:1.
[29] **Ex, 21**, PRINSTON00078809.
[30] **Ex. 21**, PRINSTON00078809.
[31] **Ex. 22**, TORRENT-MDL2875-00072650; **Ex. 23**, Sushil Jaiswal Dep. at 67:21-24, 68:1-7; **Ex. 24**, TEVA-MDL2875-00001886; **Ex. 25**, TEVA-MDL2875-00013107; **Ex. 26**, Daniel Barreto Dep. Tr. 106:23-108:16.
[32] **Ex. 27**, PRINSTON00078386.
[33] **Ex. 27**, PRINSTON00078386.
[34] **Ex. 28**, PRINSTON00073120.
[35] **Ex. 28**, PRINSTON00073120.

[redacted]

c) The Root Causes of the ZHP Valsartan API Contamination

[redacted]

d) The ZHP Contamination Levels

[redacted]

[36] **Ex. 29**, ZHP00076653.
[37] **Ex. 30**, PRINSTON00162373.
[38] **Ex. 31**, ZHP01843066 at -76.
[39] **Ex. 28**, PRINSTON00073120.
[40] **Ex. 32**, Min Li Dep. at 82:14-90:2, 92:11-20.
[41] **Ex. 32**, Min Li Dep. at 82:14-90:2, 92:11-20.
[42] **Ex. 20**, Hai Wang Dep. at 93:10-16, 154:5-11.

[redacted]

e) **It was Foreseeable That ZHP's TEA and Zinc Chloride API Manufacturing Processes for Valsartan Would Result in Nitrosamine Formation**

[redacted]

f) **ZHP Failed to Conduct an Adequate Risk Assessment with Regard to the Manufacturing Process Changes**

[redacted]

[43] **Ex. 33**, ZHP00079913, at -20-28.
[44] **Ex. 34**, PRINSTON75797 at -846.
[45] **Ex. 35**, ZHP 433.
[46] **Ex. 35**, ZHP 433.
[47] **Ex. 35**, ZHP 433.

[redacted]

g) ZHP Failed to Conduct Necessary Pilot Scale Testing to Ensure its Valsartan API Process Was Not Resulting in Unknown Impurities

[redacted]

[48] **Ex. 36**, ZHP01427917.
[49] **Ex. 37**, ZHP00004363 at -76.
[50] This language was ultimately removed from the final version.
[51] **Ex. 38**, ZHP00662283 at -308.
[52] **Ex. 39**, Eric Tsai Dep. at 34:6-36:12.

[redacted]

h) ZHP's Manufacturing Operations Were "[redacted]"

[redacted]

[53] **Ex. 39**, Eric Tsai Dep. at 34:6-36:12.
[54] **Ex. 29**, ZHP00076653.
[55] **Ex. 40**, ZHP01843099.
[56] **Ex. 36**, ZHP01427917.

[redacted]

i) ZHP Failed to Investigate Numerous Unknown Peaks on Testing of API

[redacted]

[57] **Ex. 41**, PRINSTON00463786.
[58] **Ex. 41**, PRINSTON00463786.
[59] *See* Quick Decl. ¶¶ 103-128.
[60] **Ex. 42**, ZHP01748896.
[61] **Ex. 43**, ZHP02630924; Ex. 44, ZHP02118072; Ex. 45 ZHP02118712.
[62] **Ex. 46**, ZHP00007223.

j) ZHP Easily Could Have Manufactured Valsartan Free of Nitrosamine Contamination

[redacted]

2. The Mylan Defendants

Defendant Mylan was vertically integrated and supplied valsartan API to Mylan's FD manufacturing facilities, and also supplied valsartan API to its sole external United States FD customer, Defendant Teva.[64] Mylan had three (3) FDA-approved VCD ANDAs, the first of which was approved in September 2012. All Mylan VCDs "sold in the U.S. [was sold] pursuant to one of [Mylan's] three ANDAs" approved by the FDA for Mylan VCDs.[65]

During the entirety of the Mylan class period (September 21, 2012 through December 4, [redacted]

[63] **Ex. 46**, ZHP01344159.
[64] **Ex. 47**, Derek Glover Dep. at 721:7-9; **Ex. 48**, MYLAN-MDL2875-00429120, at 15.
[65] **Ex. 47**, Derek Glover Dep. at 641:16-642-21.
[66] These dates are associated with FDA approval of Mylan's first VCD in the United States, valsartan hydrochlorothiazide ("valsartan HCTZ"), and Mylan's final recall of all remaining lots of VCDs within expiry, respectively. **Ex. 49**, Wayne Talton. Dep. at 144:24-145:8; 615:17-617:1; **Ex. 50**, Pl-Talton 13 (Mylan expanded recall announcement dated December 4, 2021).
[67] **Ex. 47**, Glover Dep. at 391:11-13, 619:5-620:1; **Ex. 51** Daniel Snider Dep. at 63:6-64:1.
[68] **Ex. 51**, Daniel Snider Dep. at 220:3-13.

[redacted]

a) **Mylan's Valsartan API Was "Adulterated" During the Class Period, and Distributed, Sold, and Dispensed Illegally to Class Members**

[redacted]

b) **All of Mylan's VCDs Were Manufactured at Non-cGMP Compliant Facilities**

[redacted]

[69] **Ex. 51**, Daniel Snider Dep. at 114:2-117:8, 145:6-9.
[70] **Ex. 52**, Jyothibasu Abbenini Dep.at 151:8-152:15.
[71] **Ex. 53**, Pl-Gomas 5.
[72] **Ex. 54**, Walt Owens Dep. 84:3-86:9; *see also* **Ex. 197**, Pl-Owens 5 (MYLAN-MDL2875-00392396 ("[redacted].
[73] **Ex. 55**, Cass Bird Dep. 64:7-15 (Mylan's Recall Coordinator confirming that Mylan recalled all lots within expiry of its VCDs).

[redacted]

c) [redacted]

[redacted]

[74] **Ex. 56**, Kim Kupec Dep. at 66:9-18; 161:8-11; **Ex. 48**, MYLAN-MDL2875-00429120, at 15.
[75] **Ex. 55**, Cass Bird Dep. at 106:2-7.
[76] **Ex. 47**, Derek Glover Dep. at 668:8-670:10; **Ex. 194**, Pl-Glover-54, at 2 (Nov. 5, 2019 Unit 8 Warning Letter).
[77] **Ex. 47**, Derek Glover Dep. at 680:1-682:10.
[78] *See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspections-database-frequently-asked-questions (last visited November 8, 2021).
[79] [redacted]

[redacted]

[80] **Ex. 51**, Daniel Snider Dep. at 237:12-238:1, 260:16-262:14; **Ex. 47**, Glover Dep at 439:1-440:7.
[81] **Ex. 51**, Daniel Snider Dep. at 261:20-262:14.
[82] **Ex. 51**, Daniel Snider Dep. at 209:16-210:6; 208:8-216:13.
[83] **Ex. 58**, Pl-Glover 8; Ex. 59, Pl-Glover 9; **Ex. 47**, Glover Dep at 100:6-101:3; **Ex. 51**, Daniel Snider Dep. at 128:14-17.
[84] **Ex. 59**, MYLAN-MDL2875-00421388; **Ex. 60**, MYLAN-MDL2875-00421389.
[85] **Ex. 60**, MYLAN-MDL2875-00421389, at -395.
[86] **Ex. 47**, Derek Glover Dep. at 82:2-6.

[redacted]

d) [redacted]

[redacted]

[87] **Ex. 61**, Pl-Owens 13 (Sethi *et al., Genotoxic impurities evaluation in Active Pharmaceutical Ingredients (API)/Drug Substance*, 8(12) Der Pharmacia Lettre, 234-243 (2016)).
[88] **Ex. 47**, Derek Glover Dep. at 835:5-19, 851:9-852:17, 856:9-857:21.
[89] **Ex. 47**, Derek Glover Dep. at 855:6-13.
[90] **Ex. 47**, Derek Glover Dep. at 477:21-481:23; **Ex. 51**, Daniel Snider Dep. at 362:17-363:7; **Ex. 62**, Antonyraj Gomas Dep. at 139:2-141:4; *see also* **Ex. 195**, Pl-Glover-56; **Ex. 196**, Pl-Glover-57.
[91] **Ex. 63**, Pl-Snider-19, at 83 ([redacted].
[92] **Ex. 49**, Wayne Talton Dep. at 191:20.

[redacted]

e) [redacted]

f) [redacted]

Mylan currently manufactures valsartan API pursuant to a process (called VAA) which

[93] **Ex. 54**, Walt Owens Dep. at 206:16-207:19.
[94] **Ex. 54**, Walt Owens Dep. at 200:20-201:14.
[95] **Ex. 56**, Kim Kupec Dep. at 238:20-239:19.
[96] **Ex. 64**, MYLAN-MDL2875-00281315.
[97] **Ex. 55**, Cass Bird Dep. at 95:13-96:5 [redacted]; 100:3-101:16 [redacted]; **Ex. 62**, Antonyraj Gomas Dep. at 326:2-10 (agreeing that "every or nearly every single API batch of VLN or VST API valsartan us[ed] recovered o-xylene … [according to] the batch data ….").

[redacted]

3. The Teva Defendants

a) Teva Sourced Both ZHP API and Mylan API

[redacted]

b) Teva Sold "Adulterated" VCDs During the Class Period

[redacted]

[98] **Ex. 51**, Daniel Snider Dep. at 152:19-154:23.
[99] **Ex. 54**, Walt Owens Dep. at 215:23-218:10.
[100] **Ex. 65**, Teva Dep. 230 at Tab 3 (Teva ZHP & Mylan API Lot Information Spreadsheets).
[101] **Ex. 66**, TEVA-MDL2875-00549883 at p.1 of 4; **Ex. 67**, TEVA-MDL2875-00049024; **Ex. 68**, TEVA-MDL2875-00737506; **Ex. 17**, Anthony Binsol Dep. at 56:2 to 60:7.
[102] **Ex. 69**, TEVA-MDL2875-00320637 (cover email attaching final Teva audit report of Mylan Unit 8); **Ex. 70**, TEVA-MDL2875-00320639, at -640, -641, -665, 671 (final Teva audit report of Mylan Unit 8); **Ex. 71**, Narendra Vadsola Dep. at 364:1 to 364:20.
[103] **Ex. 72**, TEVA-MDL2875-00020519; **Ex. 73**, TEVA-MDL287500549882; **Ex. 26**, Daniel Barreto Dep. at 167:8 to 173:22.
[104] **Ex. 74**, TEVA-MDL2875-00546489; **Ex. 66**, TEVA-MDL2875-00549883.

[redacted]

c) Teva Expected ZHP and Mylan to Make Non-Adulterated Valsartan API But Did Not Adequately Ensure This Occurred

[redacted]

[105] **Ex. 75**, TEVA-MDL2875-00103248; **Ex. 3**, Claire Lyons Dep. at 130:3 to 132:2.
[106] **Ex. 76**, TEVA-MDL2875-00042637; **Ex. 26**, Daniel Barreto Dep. at 201:10 to 202:14, 275:24 to 276:5, 367:9 to 368:2.
[107] **Ex. 77**, TEVA-MDL2875-00048605, at p.61 of 61.
[108] **Ex. 77**, TEVA-MDL2875-00048605 at pp.58-59 of 61.
[109] **Ex. 77**, TEVA-MDL2875-00048605 at pp.58-59 of 61; **Ex. 3**, Claire Lyons Dep. at 248:1-24.
[110] **Ex. 17**, Anthony Binsol Dep. at 47:14-24, 50:1 to 51:11, 54:2-16, 60:8 to 61:18, 96:6 to 97:7, 102:4 to 103:4, 108:1 to 109:8, 121:5 to 122:21.
[111] **Ex. 78**, TEVA-MDL2875-00514869; **Ex. 17**, Anthony Binsol Dep. at 204:5 to 205:7.

[redacted]

i. Teva Failed to Ensure That ZHP Valsartan API Was Not Adulterated and Made in a cGMP-Compliant Manner

[redacted]

[112] **Ex. 66**, TEVA-MDL2875-00549883 at p.1 of 4; **Ex. 67**, TEVA-MDL2875-00049024; **Ex. 70**, TEVA-MDL2875-00320639 at -641.
[113] **Ex. 13**, TEVA-MDL2875-00280442; **Ex. 26**, Daniel Barreto at 62:5 to 63:6.
[114] **Ex. 79**, TEVA-MDL2875-00244213.
[115] **Ex. 80**, TEVA-MDL2875-00107585.
[116] **Ex. 80**, TEVA-MDL2875-00107585.
[117] **Ex. 81**, TEVA-MDL2875-00108342; **Ex. 82**, Jens Nassall Dep. at 59:5 to 64:3.
[118] **Ex. 83**, TEVA-MDL275-0399168, at -187.
[119] **Ex. 84**, TEVA-MDL2875-00118147, at -154.

[redacted]

[120] **Ex. 85**, TEVA-MDL2875-0399168, at -233-245; **Ex. 84**, TEVA-MDL2875-00118147, at -168.
[121] **Ex. 86**, TEVA-MDL2875-00781611.
[122] **Ex. 87**, ZHP009129692.
[123] **Ex. 87**, ZHP009129692.
[124] **Ex. 88**, TEVA-MDL2875-00522655.
[125] **Ex. 88**, TEVA-MDL2875-00522655; **Ex. 71**, Narendra Vadsola Dep. at 260:4-14.
[126] **Ex. 89**, TEVA-MDL2875-00073283.
[127] **Ex. 90**, TEVA-MDL2875-00400391; **Ex. 71**, Narendra Vadsola Dep. at 260:18 to 261:1, 269:23 to 272:16, 283:9 to 287:15.

[redacted]

ii. Teva Failed to Ensure That Mylan Valsartan API Was Not Adulterated and Made in a cGMP-Compliant Manner

[redacted]

[128] **Ex. 71**, Narendra Vadsola Dep. at 268:1-23.
[129] **Ex. 91**, TEVA-MDL2875-00423475.
[130] **Ex. 91**, TEVA-MDL2875-00423475 [redacted]. *See* **Ex. 82**, Jens Nassall Dep. at 59:5 to 64:3; **Ex. 81**, TEVA-MDL2875-00108342.
[131] **Ex. 26**, Daniel Barreto Dep. at 74:22 to 76:23.
[132] **Ex. 26**, Daniel Barreto Dep. at 69:20 to 75:2, 360:15-18.
[133] *See* Quick Decl. ¶¶ 152-54.
[134] **Ex. 92**, TEVA-MDL2875-00247059; **Ex. 93**, TEVA-MDL2875-00318831.
[135] **Ex. 71**, Narendra Vadsola Dep. at 319:1 to 326:9; *see also* Quick Decl. ¶ 154.

[redacted]

[136] **Ex. 94**, TEVA-MDL2875-00549885.
[137] **Ex. 76**, TEVA-MDl2875-00042637, at -648; **Ex. 95**, TEVA-MDL2875-00154157, at -158-59; **Ex. 26**, Daniel Barreto Dep. at 282:1 to 286:10.
[138] **Ex. 96**, TEVA-MDL2875-00073603; **Ex. 97**, TEVA-MDL2875-00042885; **Ex. 98**, TEVA-MDL2875-00137965; **Ex. 99**, TEVA-MDL2875-00409210; **Ex. 100**, TEVA-MDL2875-00043320.
[139] **Ex. 101**, TEVA-MDL2875-00159226.
[140] **Ex. 102**, TEVA-MDL2875-00409313; **Ex. 3**, Claire Lyons Dep. at 191:14 to 194:16, 206:21 to 208:14.
[141] **Ex. 97**, TEVA-MDL2875-00042885; **Ex. 103**, TEVA-MDL2875-00164299.
[142] **Ex. 104**, TEVA-MDL2875-00159234 (internal FAQ for recall identifying November 26, 2018 as recall date); **Ex. 65**, Teva Dep. Ex. 230 at Tab 1 (indicating last date of sale November 28, 2018).

4. The Torrent Defendants

a) Torrent's API

[redacted]

b) Torrent's Valsartan was "Adulterated" During the Class Period

[redacted]

[143] **Ex. 105**, TORRENT-MDL2875-00003433; **Ex. 106**, Dawn Chitty, Dep. at 157:2-7.
[144] **Ex. 107**, Dhrumit Shah Dep. at 20-22.
[145] **Ex. 23**, Sushil Jaiswal Dep. at 201-202; **Ex. 108**, TORRENT-MDL2875-00072590; **Ex. 109**, TORRENT-MDL2875-00072457.
[146] **Ex. 110**, PRINSTON00158177 at 15.
[147] **Ex. 23**, Sushil Jaiswal Dep. at 63:1-6.
[148] **Ex. 111**, TORRENT-MDL2875-00190373.
[149] **Ex. 23**, Sushil Jaiswal Dep. at 54:14-19; 244-251.

[redacted]

c) All of Torrents VCD's Were Manufactured at Facilities that Were Non-cGMP Compliant

[redacted]

[150] **Ex. 112**, ZHP02563814; Ex. 113, Reddy Neravetla Dep at 54-57.
[151] **Ex. 114**, TORRENT-MDL2875-00366172.
[152] **Ex. 115**, TORRENT-MDL2875-00211433; **Ex. 116**, FDA Nitrosamine Announcement, Feb. 28, 2019.
[153] **Ex. 117**, TORRENT-MDL2875-00135398.
[154] **Ex. 116**, FDA Nitrosamine Announcement, Feb. 28, 2019.
[155] **Ex. 23**, Sushil Jaiswal, Dep. at 94-95.
[156] **Ex. 118**, TORRENT-MDL2875-00004360; **Ex. 119**, TORRENT-MDL2875-00004357; 120, TORRENT-MDL2875-00004358.
[157] **Ex. 120**, TORRENT-MDL2875-00004358.
[158] **Ex. 121**, TORRENT-MDL2875-00004352.

[redacted]

d) Torrent Should Have Been Aware of the Potential for Nitrosamine Formation

[redacted]

[159] **Ex. 121**, TORRENT-MDL2875-00004352.
[160] **Ex. 23**, Sushil Jaiswal Dep. at 320-328.
[161] **Ex. 122**, TORRENT-MDL2875-00516430; **Ex. 123**, TORRENT-MDL2875-00516416; **Ex. 124**, TORRENT-MDL2875-00516418.
[162] **Ex. 23**, Sushil Jaiswal Dep. at 334-335.
[163] **Ex. 125**, TORRENT-MDL2875-00000149; **Ex. 126**, TORRENT-MDL2875-00003958 at 297-320.
[164] **Ex. 126**, TORRENT-MDL2875-00003958 at 297-320.

e) Torrent Wrongly Relied on ZHP to Certify that the Valsartan Manufacturing Process Did Not Produce Geonotoxic Impurities

[redacted]

5. Hetero Defendants

a) Hetero API and FD

[redacted]

[165] **Ex. 23**, Sushil Jaiswal Dep. at 182-184.
[166] **Ex. 127**, TORRENT-MDL2875-00007067.
[167] **Ex. 127**, TORRENT-MDL2875-00007067.
[168] **Ex. 23**, Sushil Jaiswal Dep. at 183-184.
[169] **Ex. 128**, P.N. Gowda Dep. at 54:15-23; **Ex. 129**, HETERO 49; *see also* (https://www.fda.gov/media/129111/download) (last visited November 8, 2021).

[redacted]

b) Hetero Failed to Perform the Required Risk Assessment that Would Have Prevented NDMA Contaminated Valsartan From Being Sold

[redacted]

[170] **Ex. 130** Ronald Cerminaro Dep. at 18:1-9; 18:24-19:1-16; Ex. 131, CAM 2; **Ex. 128**, P.N. Gowda Dep. at 39:9-14.
[171] **Ex. 130**, Ronald Cerminaro Dep. at 19:3-16.
[172] **Ex. 132**, B.V. Ramarao Dep. at 143:14-147, 372:15-373:23, 392:22-393:16.
[173] **Ex. 133**, Manoranjan Kumar Dep. at 116:8-24.
[174] **Ex. 128**, P.N. Gowda Dep. at 15:15-23, 78:6-9; **Ex. 134**, HLL 55, HLL00554746; *see also* https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/camber-pharmaceuticals-inc-issues-voluntary-nationwide-recall-valsartan-tablets-usp-40mg-80mg-160mg (last accessed November 8, 2021).
[175] **Ex. 132**, B.V. Ramarao Dep. at 376:15-377:4.
[176] **Ex. 132**, B.V. Ramarao Dep. at 105:6-106:15, 110:18-21.

[redacted]

6. The Aurobindo Defendants

a) Aurobindo API

[redacted]

[177] **Ex. 132**, B.V. Ramarao Dep. at 96:9-97:15, 172:5-173:15.
[178] **Ex. 132**, B.V. Ramarao Dep. at 342:14-19, 377:5-20.
[179] **Ex. 135**, Blessy Johns Dep. at 14:6-24.
[180] **Ex. 136**, Johns 43.
[181] **Ex. 135**, Blessy Johns Dep. at 390:15-391:2.
[182] **Ex. 137**, Ambati Rama Rao Dep. at 222:13-16.

[redacted]

[183] **Ex. 138**, Sanjay Singh Dep. Tr., at 391:3-16.
[184] **Ex. 139**, Rao 143 (APL-MDL 2875-0504366 at 0504369).
[185] **Ex. 137**, Ambati Rama Mohana Rao Dep. at 180:4-183:19.
[186] **Ex. 138**, Sanjay Singh Dep. at 295:12-296:11.
[187] **Ex. 137**, Ambati Rama Mohana Rao Dep. at 181:11-23.
[188] **Ex. 138**, Sanjay Singh Dep. at 373:12-375:10.
[189] **Ex. 138**, Sanjay Singh Dep. at 373:12-375:10.

[redacted][191]

b) Aurobindo's Valsartan Was "Adulterated" During the Class Period, and Distributed, Sold and Dispensed Illegally to Class Members

[redacted]

[190] **Ex. 139**, Rao 143 (APL-MDL 2875-0504366 at 0504398).
[191] **Ex. 138**, Sanjay Singh Dep. at 387:15-389:4.
[192] **Ex. 137**, Ambati Rama Mohana Rao Dep. at 115:17-20.
[193] **Ex. 138**, Sanjay Singh Dep. at 237:9-17.
[194] **Ex. 138**, Sanjay Singh Dep at 239:21-240:6.

[redacted]

[195] **Ex. 138**, Sanjay Singh Dep at 237:18-239:19.
[196] **Ex. 140**, Jasleen Gupta Dep. at 207:17-24.
[197] **Ex. 141**, Gorijavolu 24 (Auro-MDL 2875-0092698).
[198] **Ex. 142**, Prasad Gorijavolu Dep. at 130:18-131:23.
[199] **Ex. 142**, Prasad Gorijavolu Dep. at 157:1-9.

[redacted]

c) All of Aurobindo's API Was Manufactured at a Facility that Was Non-cGMP Compliant

[redacted]

d) Aurobindo Failed to Reasonably Investigate its Valsartan After Having Constructive Knowledge of the Potential for Nitrosamine Formation

[redacted]

[200] **Ex. 142**, Prasad Gorijavolu Dep. at 167:12-14.
[201] **Ex. 135**, Blessy Johns Dep. at 14:6-13.
[202] **Ex. 135**, Blessy Johns Dep. at 14:6-13.
[203] **Ex. 143**, Johns 61 (Auro-MDL 2875-0101496 at 0101498).
[204] **Ex. 144**, Johns 63 (APL-MDL 2875-0023903 at 0023964).

[redacted]

e) Aurobindo Made Affirmative Representations to Valsartan Customers That the Product Was Safe Without Actually Testing It

[redacted]

[205] **Ex. 145**, Doshi 15 ("FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)").
[206] **Ex. 145**, Doshi 15 ([redacted]); **Ex. 140**, Jasleen Gupta Dep. at 105:23-106:5 ([redacted]").
[207] **Ex. 146**, Johns 54 (Auro-MDL 2875-0087922 at 0087922).
[208] **Ex. 146**, Johns 54 (Auro-MDL 2875-0087922 at 0087922).
[209] **Ex. 135**, Johns Dep. at 177:4-19.
[210] **Ex. 147**, Steve Lucas Dep. at 92:7-19.

[redacted]

f) All Batches of Aurobindo API Manufactured for U.S. Market Were Manufactured with Recovered Tri-N-Butyl Tin Chloride from Lantech, So Aurobindo Could Not Assure that Any Given Batch Would be Uncontaminated after the Manufacturing Process

[redacted]

g) Aurobindo Easily Could Have Manufactured Valsartan Free of Nitrosamine Contamination

[redacted]

[211] **Ex. 135**, Johns Dep. at 130:15-133:1.
[212] **Ex. 140**, Jasleen Gupta Dep. at 304:22-305:8; **Ex. 148**, Gupta 100 (Auro-MDL 2875-0085416 at 0085416).
[213] **Ex. 149**, Gupta 75 (Auro-MDL2875-0105697 at 0105697); **Ex. 150**, Gupta 76 (Auro-MDL2875-0085169).
[214] **Ex. 151**, Cesar Cedeno Dep. at 40:2-7.
[215] **Ex. 152**, Rao 143 (APL-MDL 2875-0504366 at 0504369).

[redacted]

C. The Retail Pharmacy Defendants Facts

The Retail Pharmacy Defendants are Walgreens Boots Alliance, Inc. ("Walgreens"), CVS Health Corporation ("CVS Health"), Walmart Stores, Inc. ("Wal-Mart"), Rite-Aid Corporation ("Rite-Aid"), Express Scripts, Inc. ("Express Scripts"), The Kroger, Co., ("Kroger"), OptumRx, and Albertson's LLC ("Albertsons") (collectively "The Retail Pharmacy Defendants"). *See* Consolidated Third Amended Economic Loss Class Action Complaint ("SAC") (D.E. 1708, at ¶¶ 106-141).

Common evidence will show that each of the Retail Pharmacy Defendants played a critical role – actually dispensing the products to the consumer class members, and profiting from the sale of these contaminated drugs. Indeed, each Retail Pharmacy Defendant was responsible for sourcing the VCDs that were ultimately sold to the class members. The Economically worthless VCDs that the Retail Pharmacy Defendants sourced for the class members were contaminated, and as a result were adulterated and misbranded, and economically worthless.

1. Walmart

[redacted]

[216] **Ex. 137**, Ambati Rama Mohana Rao Dep. at 82:4-18.
[217] **Ex. 137**, Ambati Rama Mohana Rao Dep. at 83:24-84:9.

[redacted]

[218] **Ex. 153**, Dick Derks Dep. at 24:18-25:2
[219] **Ex. 153**, Dick Derks Dep. at 21:23-22:1-5.
[220] **Ex. 153**, Dick Derks Dep. at 26:6-27:9.
[221] **Ex. 153**, Dick Derks Dep. at 30:2-20.
[222] **Ex. 153**, Dick Derks Dep. at 31:2-13.
[223] **Ex. 153**, Dick Derks Dep. at 31:22-32:13.
[224] **Ex. 153**, Dick Derks Dep. at 34:7-35:13.
[225] **Ex. 153**, Dick Derks Dep. at 41:9-20.

[redacted]

2. Walgreens

[redacted]

[226] **Ex. 153**, Dick Derks Dep. at 46:18-47:19
[227] **Ex. 153**, Dick Derks Dep. at 46:18-47:19.
[228] **Ex. 153**, Dick Derks Dep. at 49:16-50:9.
[229] **Ex. 154**, Dadrion Gaston Dep. at 171:3-172:32.
[230] **Ex. 155**, Stacy Zulueta Dep. at 226:8-228:13.
[231] **Ex. 155**, Stacy Zulueta Dep. at 226:8-228:13.
[232] **Ex. 155**, Stacy Zulueta Dep. at 232:2-8.
[233] **Ex. 156**, Walmart 25.

[redacted]

3. CVS

[redacted][244]

[234] **Ex. 157**, Catherine Stimmel Dep. at 74:24-75:17.
[235] **Ex. 158**, Brian Strong Dep. at 27:8-15.
[236] **Ex. 158**, Brian Strong Dep. at 29:5-13.
[237] **Ex. 158**, Brian Strong Dep. at 29:14-22.
[238] **Ex. 157**, Catherine Stimmel Dep. at 74:24-75:17.
[239] **Ex. 157**, Catherine Stimmel Dep. at 131:2-9.
[240] **Ex. 157**, Catherine Stimmel Dep. at 132:22-133:20.
[241] **Ex. 157**, Catherine Stimmel Dep. at 137:16-138:10.
[242] **Ex. 159**, Zackary Mikulak Dep. at 17:11-18:14.
[243] **Ex. 157**, Catherine Stimmel Dep. at 173:2-14; 174:2-11.
[244] **Ex. 160**, John Holderman Dep. at 20:8-22.

[redacted]

[245] **Ex. 160**, John Holderman Dep. at 22:17-23:23.
[246] **Ex. 160**, John Holderman Dep. at 21:2-22:2.
[247] **Ex. 160**, John Holderman Dep. at 80:22-81:5; 88:9-91:9; 92:13-24.
[248] **Ex. 161**, Scott Griffin Dep. at 66:7-13.
[249] **Ex. 161**, Scott Griffin Dep. at 70:1-16; 174:2-11.
[250] **Ex. 161**, Scott Griffin Dep. at 73:19-76:19.
[251] **Ex. 161**, Scott Griffin Dep. at 75:7-21.

4. Rite-Aid

[redacted]

[redacted] **162**, Owen McMahon Dep. at 21:25-24:9.
[253] **Ex. 162**, Owen McMahon Dep. at 24:11-25:3.
[254] **Ex. 162**, Owen McMahon Dep. at 30:6-35:7.
[255] **Ex. 162**, Owen McMahon Dep. at 48:15-24.
[256] **Ex. 162**, Owen McMahon Dep. at 53:11-16; 58:2-10.
[257] **Ex. 162**, Owen McMahon Dep. at 53:25-54:6; 57:1-16.
[258] **Ex. 163**, Scott Jacobson Dep. at 26:22-27:13.
[259] **Ex. 163**, Scott Jacobson Dep. at 31:21-32:14.

[redacted]

5. Kroger

[redacted]

[260] **Ex. 163**, Scott Jacobson Dep. at 71:16-74.
[261] **Ex. 164**, Britt Turner Dep. at 66:23-67:12.
[262] **Ex. 164**, Britt Turner Dep. at 66:10-22.
[263] **Ex. 164**, Britt Turner Dep. at 27:5-10.
[264] **Ex. 164**, Britt Turner Dep. at 105:16-106:3.
[265] **Ex. 164**, Britt Turner Dep. at: 66:10-22.
[266] **Ex. 164**, Britt Turner Dep. at 66:23-67:12
[267] **Ex. 164**, Britt Turner Dep. at 27:11-16, 32:4-10,32:18-22.
[268] **Ex. 164**, Britt Turner Dep. at 70:13-16.
[269] **Ex. 164**, Britt Turner Dep. at 70:17-23.
[270] **Ex. 164**, Britt Turner Dep. at 102:3-12.

[redacted]

6. OptumRx

[redacted]

[271] **Ex. 164**, Britt Turner Dep. at 36:23-37:6, 37:18-38:1.
[272] **Ex. 164**, Britt Turner Dep. at 39:8-17.
[273] **Ex. 164**, Britt Turner Dep. at 82:18-21.
[274] **Ex. 164**, Britt Turner Dep. at 82:22-83:6.
[275] **Ex. 164**, Britt Turner Dep. at 41:15-21, 43:19-44:6.
[276] **Ex. 164**, Britt Turner Dep. at 44:7-11.
[277] **Ex. 164**, Britt Turner Dep. at 44:12-22.
[278] **Ex. 164**, Britt Turner Dep. at 46:7-11.
[279] **Ex. 165**, Wendy Woon-Fat Dep. at 64:13-65:11.
[280] **Ex. 165**, Wendy Woon-Fat Dep. at 34:16-20; 118:12-15.
[281] **Ex. 165**, Wendy Woon-Fat Dep. at 114:5-15; 117:1-3; 122:23-123:5;123:17-20; 126:17-127:3.

[redacted]

[282] **Ex. 165**, Wendy Woon-Fat Dep. at 128:1-8.
[283] **Ex. 165**, Wendy Woon-Fat Dep. at 142:22-143:7; **Ex. 166**, Optum 17.
[284] **Ex. 167**, Steven Taylor Dep. at 206:2-208:24.
[285] **Ex. 168**, Ketan Patel Dep. at 270:18-271:19.
[286] **Ex. 168**, Ketan Patel Dep. at 272:5-273:4.
[287] **Ex. 165**, Wendy Woon-Fat Dep. at 40:22-41:16, 90:3-7.
[288] **Ex. 165**, Wendy Woon-Fat Dep. at 145:21-147:1.
[289] **Ex. 165**, Wendy Woon-Fat Dep. at 31:3-11.
[290] **Ex. 165**, Wendy Woon-Fat Dep. at 50:4-7.
[291] **Ex. 165**, Wendy Woon-Fat Dep. at 164:7-166:1.
[292] **Ex. 167**, Steven Taylor Dep. at 213:3-6.

7. Express Scripts Pharmacy

[redacted]

8. Albertson's

[redacted]

[293] **Ex. 169**, Susan Peppers Dep. at 26:3-12.
[294] **Ex. 169**, Susan Peppers Dep. at. 27:3-8.
[295] **Ex. 169**, Susan Peppers Dep. at 30:13-31:3.
[296] **Ex. 169**, Susan Peppers Dep. at 27:14-24.
[297] **Ex. 169**, Susan Peppers Dep. at 27:20-24.
[298] **Ex. 169**, Susan Peppers Dep. at 28:5-15

[redacted]

[299] **Ex. 170**, Erin Shaal Dep. at 65:17-66:1.
[300] **Ex. 170**, Erin Shaal Dep. at 51:24-52:4.
[301] **Ex. 170**, Erin Shaal Dep. at 46:6-11.
[302] **Ex. 170**, Erin Shaal Dep. at 47:5-19.
[303] **Ex. 170**, Erin Shaal Dep. at 279:10-280:8.
[304] **Ex. 170**, Erin Shaal Dep. at 81:13-24; 86:13-20; 180:3-16.
[305] **Ex. 170**, Erin Shaal Dep. at 305:7-21; 307:4-17.
[306] **Ex. 170**, Erin Shaal Dep. at 305:22-306:6.
[307] **Ex. 170**, Erin Shaal Dep. at 347:21-348:20.

D. The Wholesaler Defendants

The three named Wholesaler Defendants in this class action are Cardinal Health, Inc. ("Cardinal Health"), McKesson Corporation ("McKesson"), and AmerisourceBergen Corporation ("AmerisourceBergen") (collectively referred to herein as the "Wholesaler Defendants"). The Wholesaler Defendants purchased, among other things, generic drugs (including VCDs) from FD Manufacturer Defendants and sold or otherwise supplied those generic pharmaceuticals to various Retail Pharmacy Defendants. As the common evidence will prove, the Wholesaler Defendants entered into specific wholesale supplier agreements with the Manufacturer Defendants and generally acted as the intermediary and/or designated supplier for the Manufacturer Defendants for the generic drugs, including the economically worthless VCDs, which were provided to the Retail Pharmacy Defendants and ultimately paid for by Class Members.

1. Cardinal Health, Inc.

[redacted]

[308] **Ex. 171**, Martin Igel (Cardinal) Dep. at 44:24-45:20.
[309] **Ex. 171**, Martin Igel (Cardinal) Dep. at 36:5-37:19; 124:24-126:19.
[310] **Ex. 171**, Martin Igel (Cardinal) Dep. at 37:20-38:11; 54:22-55:5.

[redacted]

2. McKesson Corporation

[redacted]

E. The Wholesaler Defendants' Supply and Service Agreements.

1. [redacted]

[redacted]

[311] **Ex. 172**, Cardinal 41.
[312] **Ex. 172**, McKesson 19.
[313] **Ex. 173**, Amerisource 14.
[314] **Ex. 174**, Amerisource 11.

[redacted]

2. The Representations and Warranties Contained in the Wholesale Supplier Agreements Between the Wholesaler Defendants and the Manufacturer Defendants.

[redacted]

[315] **Ex. 171**, Martin Igel (Cardinal) Dep. at 55:6-12; 60:8-14; 65:10-17, 113:15-114:6, 134:14-138:1; **Ex. 175**, McKesson 13.; Ex. 176 Heather Odenwelder (Amerisource) Dep. at 86: 2-5; 128:6-19; 131: 9-24; 132:1-5, 9-24; 133:7-22; 178:2-16, 22-24; 179:1-14.

[316] **Ex. 171**, Martin Igel (Cardinal) Dep. at 72:16-74:11,116:21-117:5; **Ex. 177**, McKesson 15; **Ex. 178**, Amerisource 23.

[317] **Ex. 177** at §7.A (2)(h); **Ex. 179**, Julie Webb (Cardinal) Dep. at 14:8-15:10; 16:4-23; **Ex. 171**, Martin Igel (Cardinal) Dep. at 141:6-143:6.

[318] **Ex. 179**, Julie Webb (Cardinal) Dep. at 15:18-18:11.

[319] **Ex. 171**, Martin Igel (Cardinal) Dep. at 79:17-82:24, 84:3-85:1, **Ex. 180**, Brett Harrop (McKesson), Dep. at 56:21-57:6; **Ex. 176** Heather Odenwelder (Amerisource) Dep. at 120:1-11; 135:15-24; 136:1-11, 22-24; 137:1-16.

[redacted]

3. Wholesaler Defendants Did Not Test or Require Testing of the Economically Worthless VCDs.

[redacted]

[320] **Ex. 171**, Martin Igel (Cardinal) Dep. at 117:13-119:2; **Ex. 177** at 6-7, §7.A(2); **Ex. 178** at ¶13.
[321] **Ex. 171**, Martin Igel (Cardinal) Dep. at 144:17-145:23; **Ex. 178** at 22-23 (Products will not be "adulterated, misbranded, or otherwise prohibited" under applicable law).
[322] **Ex. 171**, Martin Igel (Cardinal) Dep. at 79:15-82:12; **Ex. 180**, Brett Harrop (McKesson) Dep. at 59:2-15; 59:20; 59:20-60:6; **Ex. 176** Heather Odenwelder (Amerisource) Dep. at 93:2-8.
[323] **Ex. 171**, Martin Igel (Cardinal) Dep. at 101:8-102:12, 108:22-109:13, 121:12-122:2, 156:15-158:17; **Ex. 176** Heather Odenwelder (Amerisource) Dep. at 171:23-173:16.
[324] **Ex. 179**, Julie Webb (Cardinal) Dep. at 35:10-36:10; **Ex. 181**, Sam Buckley (McKesson) Depo at 26:23-27:3, 60:4-61:19; **Ex. 176** Heather Odenwelder (Amerisource) Dep. at 171:23-173:16.

[redacted]

4. Following Notice of The Recall in July 2018, the Wholesaler Defendants Did Nothing to Ensure Other VCDs They Were Distributing Were Not Adulterated or Contaminated with Impurities.

[redacted]

IV. LAW AND ARGUMENT

A. The District Court Has "Broad Discretion" Under Rule 23 to Certify These Classes

Class certification is appropriate if the proposed class meets the requirements of Rule 23(a) and at least one subsection of Rule 23(b). The trial court "possesses broad discretion to control proceedings and frame issues for consideration under Rule 23[.]" *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 249 (3d Cir. 2016); *see also In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 035, 312 (3d Cir. 2008) ("We review a class certification order for abuse of discretion, which occurs if

[325] **Ex. 180**, Brett Harrop (McKesson) Dep. at 35:7-39:13; **Ex. 179**, Julie Webb (Cardinal) Dep. at 36:5-22; 42:12-43:2; **Ex. 176** Heather Odenwelder (Amerisource) Dep. at 99:15-24; 100:1-10; 101:4-15.
[326] **Ex. 180**, Brett Harrop (McKesson) Dep. at 45:21-46-2.
[327] **Ex. 181**, Sam Buckley (McKesson) Depo at 31:9-35:21; **Ex. 176** Heather Odenwelder (Amerisource) Dep. at 91:8-24; 92:1-15; 93:2-8; 171:23-24; 172:5-6, 20-24; 173:5-10; **Ex. 182**, Steve Mays (Amerisource) Dep. at 123:1-20; **Ex. 179**, Julie Webb (Cardinal) Dep. at 35:16-24; 36:1-22.

the district court's decision rests upon a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact.").

The Third Circuit has described the appellate standard for class certification as "deferential," *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 164 (3d Cir. 2001), which is based on a "recognition of the essentially factual basis of the certification inquiry and of the district court's inherent power to manage and control pending litigation." *Maldonado v. Ochsner Clinic Found.*, 493 F.3d 521, 523 (5th Cir. 2007) (citations and quotations omitted).

While Plaintiffs bear the burden of showing the prerequisites for class certification are met, they need not make a showing of "absolute proof." *Reyes v. Netdeposit, LLC*, 802 F.3d 469, 484 (3d Cir. 2015) (vacating and remanding denial of class certification for imposing too strict a standard of proof). Courts consider merits issues only to the extent that they are relevant to determining whether the Rule 23 prerequisites for class certification are satisfied. *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 466 (2013).

B. The "Threshold Requirements" Under Rule 23(a) and Rule 23(b)

To meet the threshold requirements of class certification under Rule 23(a), Plaintiffs must establish that (1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class. Fed. R. Civ. P. 23(a); *In re Cmty. Bank of N. Va.*, 622 F.3d 275, 290 (3d Cir. 2010). Then, Plaintiffs must satisfy at least one subsection of Rule 23(b) – in this case Rule 23(b)(3) – which requires a showing that "questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3).

C. The Proposed Class Definitions, Exclusions, and State Groupings

This Motion seeks certification of the classes and subclasses set forth in the Class Definitions Table[328] based on multistate groupings set forth in the claim-specific State Groupings Tables and Legal Authorities Tables.[329] These groupings also are reflective of this Court's MTD rulings. Plaintiffs seek certification of the following claims against the following Defendants based on these multistate groupings:

- Breach of express warranties against Manufacturer Defendants;
- Breach of implied warranties against Manufacturer Defendants and Retail Pharmacy Defendants;
- Common law fraud against Manufacturer Defendants;
- Consumer protection act claims against Manufacturer Defendants, and against the Retail Pharmacy Defendants in jurisdictions that allow such claims without a showing of intent; and
- Unjust enrichment against Wholesaler and Retail Pharmacy Defendants

D. Ascertainability Standard is Satisfied

The Third Circuit recognizes an implicit requirement that members of a Rule 23(b)(3) class be ascertainable. *Hargrove v. Sleepy's LLC*, 974 F.3d 467, 469-70 (3d Cir. 2020). Ascertainability means "'(1) the class is defined with reference to objective criteria and (2) there is a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition.'" *Id.* (quoting *Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d Cir. 2015)).

In *Hargrove*, the Third Circuit recently clarified that "at the certification stage … [w]e have held that a plaintiff need not be able to identify all class members at class certification—instead, a plaintiff need only show that class members can be identified.'' 974 F.3d at 470 (internal quotations omitted). The Third Circuit has found that business records, affidavits, and "other

[328] **Ex. 1**.
[329] **Ex. 2**.

reliable" evidence can demonstrate the ascertainability of the class members. *City Select Auto Sales Inc. v. BMW of N. Am. Inc.*, 867 F.3d 434, 441 (3d Cir. 2017).

Here, the consumer economic loss plaintiffs are seeking to certify a class of purchasers of generic products, which occurred during a particular class period. Similarly situated classes of consumer plaintiffs in pharmaceutical cases have been found to be equally ascertainable and certified in a great many cases in the antitrust context. *See, e.g.*, *In re Nexium Antitrust Litig.,* 777 F.3d 9, 23 (1st Cir. 2015)*; In re Restasis (Cyclosporing Ophthalmic Emulsion) Antitrust Litig.*, 335 F.R.D. 1 (E.D.N.Y. 2020); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.,* No. 14-cv-02503, 2017 WL 462177 (D. Mass. Oct. 16, 2017); *In re Lidoderm Antitrust Litig*., No. 14-md-02521, 2017 WL 679367 (N.D. Cal. Feb. 21, 2017; *In re Flonase Antitrust Litig.,* 284 F.R.D. 207 (E.D. Pa. 2012).

Indeed, the ascertainability standard is more easily met in this case than in the pharmaceutical pay-for-delay antitrust context. For example, this case and its facts present no issues regarding complex exclusion criteria (including, for example, so-called "brand loyalists" or other exclusions faced by antitrust plaintiffs), and because Plaintiffs' expert, Dr. Rena Conti, models damages based upon an "economic worthlessness" theory, as discussed in detail below.

1. Ascertainability of the Manufacturer Defendant Consumer Economic Loss Class Members

Prescription pharmaceutical class members are particularly identifiable, and therefore ascertainable, because an abundance of business records and data exists to track these purchases (and are, indeed, required by law to be maintained). Plaintiffs' expert, Laura Craft, the President of OnPoint Analytics, Inc., opines in her expert declaration that all approved generic drug products are issued a unique 10-digit code, called a NDC number. *See* Craft Decl. at ¶¶ 9,15. The NDC embeds details about the specific product, including the identity of the manufacturer (or labeler),

the strength, dosage form, and formulation of the drug, and the package size and type. *Id.* ¶¶ 15, 44. Further, to ensure the entire drug supply chain system integrates seamlessly, there has been a very high level of standardization in this industry. *Id.* ¶¶ 10, 15, 19, 24-32.

Because the NDC is a critical component of each transfer of a prescription drug throughout the drug supply chain, each transaction, including the transactions between the pharmacies and the consumers, is accompanied, and labeled, with the NDC code. *Id.* ¶ 15. Indeed, a transaction record is generated every time a consumer purchases a prescription drug, which identifies the consumer's personal information, the product purchased, the date of purchase, and the amount paid.[330] All Retail Pharmacy Defendants have produced patient-level data going back to at least 2012 that is sufficient to identify virtually all Consumer EL Class Members, their purchases and dates of purchase of VCDs by NDC number, and amounts paid at the point of sale. Craft Decl. ¶ 21 (collecting defense testimony on existence of data for at least ten years).

Pharmacy, health insurance, and PBM records must be made available to consumers by law. That the Class Plaintiffs' relevant time period begins in 2012 poses no issues, as pharmacies are required to keep customers' prescription drug transaction records for at least ten years due to federal Medicare and Medicaid compliance requirements. *Id.* All of these records would contain information regarding 1) the NDC number of the product which was purchased, 2) the pharmacy where it was purchased (including the physical location of such pharmacy), 3) the date it was purchased, 4) the quantity that was purchased, 5) the dosage of the product, and 6) the price paid [331] by the consumer when it was purchased. This is further confirmed by the data the Defendants

[330] **Ex. 183**, WALMART-LEE_000001, **Ex. 184**, WALGREENS-ERWIN_0000017, **Ex. 185** CVS_MDL2875_DFS_BYRDC_0000000001.

[331] The wealth of data which exists at the Pharmacy or PBM level would likewise permit feasible identification of consumers, based on objective criteria, who did not pay anything out-of-pocket

have produced to date. [332]

Moreover, as Dr. Conti states in her Declaration, common evidence will show that *every single one of the* VCDs ever manufactured, distributed, and dispensed in the United States during the respective class period(s) by the Defendants was economically worthless. Conti Decl. ¶¶ 7, 39-46. Accordingly, ascertaining the identities of the Class Members is an even more simple task than it would otherwise be. In other words, the same information that establishes ascertainability also establishes damages.

2. Ascertainability of the Wholesaler Defendant Consumer Economic Loss Class Members

For many of the same reasons as apply to the Manufacturer Classes, the Wholesaler Classes are also sufficiently ascertainable with objective evidence. The readily available NDCs will show which VCDs were sold by Manufacturers to the Wholesaler Defendants, during which time periods, at which quantities. Indeed, the Wholesaler Defendants themselves have described the wealth of data sources they have available at their disposal, all of which provides additional objective data which can be used to ascertain class members. *See, e.g.,* D.E. 478.

[redacted]

Economically worthless Products. Craft Decl. ¶¶ 36-53. By definition, these consumers are excluded from the class.

[332] **Ex. 183**, WALMART-LEE_000001, **Ex. 184**, WALGREENS-ERWIN_0000017, **Ex. 185** CVS_MDL2875_DFS_BYRDC_0000000001.

[333] **Ex. 179**, Julie Webb (Cardinal) Dep. at 14:13-15:6; **Ex. 177** at §7(a)(2)(h).

[334] **Ex. 179**, Julie Webb (Cardinal) Dep. at 15:7-8; **Ex. 181**, Sam Buckley (McKesson) Depo at 131:18-135:6; **Ex. 176** Heather Odenwelder (Amerisource) Dep. at 37:8-16; 38:4-13, 173:12-175:13.

[redacted]

[335] **Ex. 179**, Julie Webb (Cardinal) Dep. at 15:18-16:9; **Ex. 181**, Sam Buckley (McKesson) Depo at 131:18-135:6 **Ex. 176** Heather Odenwelder (Amerisource) Dep. at 42:10-18; **Ex. 186**, Feb. 11, 2021, Wholesaler Defendants' Stipulation.
[336] **Ex. 179**, Julie Webb (Cardinal) Dep. at 15:7-816:4-17:6.
[337] **Ex. 179**, Julie Webb (Cardinal) Dep. at 17:7-15; **Ex. 171**, Martin Igel (Cardinal) Dep. at 141:6-142:9.
[338] **Ex. 179**, Julie Webb (Cardinal) Dep. at. 91:9-19; **Ex. 171**, Martin Igel (Cardinal) Dep. at 266:7-271:23; **Ex. 176** Heather Odenwelder (Amerisource) Dep. at 44:9-24; 45:1, 21-22; 46:1-4; 58:2-24; 59-62; 63:1-5; 64:3-24; 65:1-21.
[339] **Ex. 187**, Cardinal 25.
[340] **Ex. 179**, Julie Webb (Cardinal) Dep. at 77:8-78:6

[redacted]

3. *Ascertainability of the Retail Pharmacy Defendant Consumer Economic Loss Class Members*

The same data that exists and can be objectively used to ascertain class membership with the Manufacturer and Wholesaler classes can likewise be used to objectively ascertain class membership within the Retail Pharmacy Classes. Indeed, the entire process of reimbursing pharmacy and consumers for end-purchases of pharmaceutical product depends on the ability to know the precise drug and packaging that was dispensed, as well as the manufacturer of the drug product. Craft Decl. ¶¶ 15-16.

As Craft opined, pharmacy log data can be aggregated programmatically to search for sales associated with relevant NDC codes. *Id.* ¶ 13. These data sources included consumer name, consumer address, pharmacy address, date of purchase, amount paid, NDC of product purchased, and quantity of product purchased. Pharmacies are required to use the same basic data fields, definitions and formats provided in the Telecommunications Guidelines developed by the National Council for Prescription Drug Programs. *Id.* ¶ 19. These guidelines were made mandatory in 2003 under regulations implementing the Health Insurance Portability and Accountability Act ("HIPAA"). *Id.* Because of these HIPAA requirements, all of the inter-related systems used by the Defendants (Manufacturers, Wholesalers, Retail Pharmacies and TPPs) use a common language to identify the products. *Id.*

Were this not enough, in this litigation itself, the Retail Pharmacy Defendants each produced consumer level dispensing data capturing detailed information of every dispensation of these economically worthless VCDs. [redacted]

[redacted]

Given the wealth of data and records for the entirety of the class period, there are enough objective criteria with which to ascertain class membership, and it is more than administratively feasible to identify these members with this data and objective criteria.

E. The Rule 23(a) Elements Are Satisfied

1. Numerosity (Rule 23(a)(1))

Numerosity is satisfied when a potential class is "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). "While '[n]o minimum number of plaintiffs is required to maintain a suit as a class action,' [the Third Circuit] has said that "generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met." *In re Modafinil*, 837 F.3d at 249–50 (citing and quoting *Stewart v. Abraham*, 275 F.3d 220, 226–27 (3d Cir. 2001)).

Numerosity is easily satisfied here. The economic loss consumer class members number into the millions based on the scope of the case and the multi-year class period. [redacted]

2. Commonality (Rule 23(a)(2))

Rule 23(a)(2) requires "questions of law or fact common to the class." A common question is one that "is capable of class-wide resolution – which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." *Wal-Mart Stores, Inc. v. Dukes,* 131 S. Ct. 2541, 2551 (2011). The Third Circuit has "set a low threshold" for this requirement. *Newton*, 259 F.3d at 183. For purposes of Rule 23(a)(2), even a

single common question of law *or* fact will do. *Id.* Additionally, "[t]he focus of the commonality inquiry is not on the strength of each plaintiff's claim, but instead is on whether the defendants' conduct was common as to all of the class members." *Rodriguez v. Nat'l City Bank*, 726 F.3d 372, 382 (3d Cir. 2013) (internal quotation and citations omitted).

Here questions common to all class members abound and include:

- Did the Manufacturer Defendants manufacture VCDs contaminated with NDMA and NDEA?
- Did the Manufacturer Defendants commit material CGMP violations at their site(s) of manufacture of VCDs?
- What was the root cause of the NDMA/NDEA contamination for each of the Manufacturer Defendants' VCDs?
- Does the Manufacturer Defendants' identification of a generic drug as the chemical equivalent to the Orange Book/USP brand name constitute an actionable express warranty"[341]?
- Does the Manufacturer Defendants' labeling of their adulterated and/or contaminated VCDs as FDA-approved valsartan amount to common law fraud, or violate states' respective consumer fraud acts?
- Did the Wholesaler Defendants owe a duty to ensure that the products they distributed into the stream of commerce were merchantable?
- Were the Wholesaler Defendants unjustly enriched by selling cheaply made and defective Valsartan products?
- Were the Retail Pharmacy Defendants unjustly enriched by selling cheaply made and defective Valsartan products?
- Did the consumer class members directly confer a benefit to the Retail Pharmacy Defendants in purchasing the economically worthless VCDs?
- Are there reliable and administratively feasible mechanism(s) for determining whether putative class members fall within the proposed class definition(s)?
- Are Class Members' damages susceptible to classwide evidence and a common formula and/or formulae?

These common questions (among others) will lead to answers common to the class, advancing the litigation for all class members "in one stroke." *Wal-Mart,* 131 S. Ct. at 2551. Since Plaintiffs' and the class's claims all arise out of a common wrong (i.e., Defendants' manufacture,

[341] *Id*. at 13.

distribution, and/or dispensing of economically worthless VCDs), which injured each of them in the same way, Rule 23(a)(2)'s commonality requirement is fulfilled here.

3. Typicality (Rule 23(a)(3))

Rule 23(a)(3) requires "the claims or defenses of the representative parties [to be] typical of the claims or defenses of the class." The Third Circuit has "set a low threshold" for this requirement as well. *Newton*, 259 F.3d at 183. Typicality is established when a plaintiff's claim arises from the same course of conduct and is based on the same legal theory as the class claims. *Id.* It is not necessary that all class members "share identical claims." *Id.* Once a plaintiff shows that claims are based on a common legal theory, typicality is satisfied because "even relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal theories or where the claim arises from the same practice or course of conduct." *Id.*

Plaintiffs' claims are typical of those of the classes. Plaintiffs and other Consumer EL Class Members were all injured in the same way (economic loss consisting of the full cost of their product) as a result of the same conduct by Manufacturer, Wholesaler, and Retail Pharmacy Defendants (i.e., Defendants' manufacture, distribution, and/or dispensing of economically worthless VCDs, which were contaminated with NDMA/NDEA and manufactured under circumstances involving substantial and material cGMP violations to the point that Defendants could not assure they were as represented).

Typicality is also satisfied by the API-based groupings of FD Manufacturer Defendants for class definitions that Plaintiffs propose in their Motion.[342] As Defendants themselves concede, the substantive liability facts of this case turn nearly exclusively on conduct that occurred at the API

[342] **Exs. 1-2**, (Class Definitions, Exclusions, State Groupings Tables ("Class Tables"))

level, which is the same across FD Defendants sourcing API from the same supplier. In addition, Plaintiffs' warranty- and fraud-based claims turn on warranties and fraudulent statements that are nearly identical for all Manufacturer Defendants (including naming the drug "valsartan" and listing it in the Orange Book,[343] and misbranding[344] it). *Newton*, 259 F.3d at 183 (stating that it is not necessary that all class members "share identical claims" and that typicality will not be precluded even when there are "relatively pronounced factual differences" when there is a "strong similarity of legal theories or where the claim arises from the same practice or course of conduct").

Typicality is also satisfied as to the Wholesaler and Retail Pharmacy Defendants. As the Wholesaler and Retail Pharmacy Defendants themselves concede, the processes for which they distribute their products to their Retail Pharmacy Customers, or the processes by which they distribute their products to their consumer customers are rooted in the regulatory framework under which they operate, and do not differ based on the individual circumstances of Consumer EL Class Members. Further, the Economic Loss Class Representatives' claims asserted against these defendants are aligned with those of other Class Members that will turn on the same common proof. *Newton*, 259 F.3d at 183.

4. Adequacy (Rule 23(a)(4))

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." "The adequacy requirement primarily examines two matters: the interests and incentives of the class representatives, and the experience and performance of class counsel." *In re Community Bank of N. Va. Mort'g Lending Pracs. Litig*., 795 F.3d 380, 392 (3d Cir. 2015).

The forty-six (46) putative Consumer Economic Loss Class Representatives have all engaged vigorously in the case, assisting in the preparation and review of lengthy Plaintiff Fact

[343] *See* D.E. 775, at 13-14.
[344] *See* D.E. 818, at 12-18.

Sheet ("PFSs"), collecting records, assisting counsel in responding to Defendants' discovery requests, reviewing pleadings, and sitting for many hours of far-reaching depositions and are committed to seeing the litigation through to its ultimate resolution.

There are also no conflicts of interest among the putative EL Class Representatives that would prevent any of them from being properly appointed by the Court as EL Class Representatives. Only an "obvious" and "fundamental conflict of interest will be sufficient to impact the adequacy analysis." *Dewey v. Volkswagen Aktiengesellschaft*, 681 F.3d 170, 183 (3d Cir. 2012); *see also In re Community Bank*, 795 F.3d at 389. "A fundamental conflict exists where some [class] members claim to have been harmed by the same conduct that benefitted other members of the class." *Dewey*, 681 F.3d at 183 (internal quotations omitted). "'To defeat the adequacy requirement … a conflict must be more than merely speculative or hypothetical.'" *In re Community Bank*, 795 F.3d at 395 (quoting *Gunnells v. Healthplan Servs., Inc.*, 348 F.3d 417, 430 (4th Cir. 2003)). Rather, to defeat class certification, "that conflict [must be] apparent, imminent, and on an issue at the very heart of the suit." *Id.* (internal quotations and citations omitted). No such conflicts exist.

The putative Consumer EL Class Representatives have also protected the Class Members' interests by retaining Proposed Consumer EL Class Counsel, who are experienced and qualified to litigate complex class actions. Proposed Consumer EL Class Counsel, along with their respective Declarations include:

- MDL Co-Lead Counsel Ruben Honik, Esq. (**Ex. 198**)
- MDL Co-Lead Counsel Conlee Whiteley, Esq. (**Ex. 199**)
- MDL PEC Counsel John R. Davis, Esq. (**Ex. 200**)

As set forth in their accompanying respective Declarations, proposed Consumer EL Class Counsel have extensive experience prosecuting class actions and complex matters involving pharmaceutical products, consumer protection, and other issues. They all serve in various roles on the Court-appointed MDL leadership, have contributed significant time and costs to the litigation, have vigorously prosecuted all aspects of this case since inception and remain fully committed going forward. As with the putative Consumer EL Class Representatives, there are no fundamental or present conflicts of interest among the putative Consumer Economic EL Counsel, and thus no need for separate counsel to represent any subclass of the Consumer EL Class Members.

F. Rule 23(b)(3) Predominance Is Satisfied

In addition to satisfying the requirements of Rule 23(a), this case also satisfies Rule 23(b)(3), which requires that "questions of law or fact common to the class members predominate over any questions affecting only individual members and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). "The Rule 23(b)(3) predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Reyes*, 802 F.3d at 488 (quotation omitted). The "focus [of the predominance inquiry] is on whether the defendant's conduct was common as to all of the class members," and "does not require the absence of all variations in a defendant's conduct or the elimination of all individual circumstances." *Id.* at 489 (citations and quotations omitted).

The resolution of this case will be driven by core questions that are common to the class and very well suited for class-wide adjudication. The predominant focus of the trial in this case will certainly be Defendants' conduct, which was directed at the class as a whole, and not the individual circumstances of any Class Members. Both the liability and damages issues here are well suited to class-wide adjudication through common sources of proof and common questions will predominate at trial.

Before moving to address predominance on a claim-by-claim basis, Plaintiffs address certain predominance issues that are applicable to a number of the claims.

1. Damages Are Easily and Readily Calculable Pursuant to a Class Wide Formula of General Application

Proof of damages is no impediment to class certification here. In her Declaration, Dr. Rena Conti, a healthcare economist and current Associate Professor of Markets, Public Policy and Law in the Questrom School of Business at Boston University, has provided a well-established, generally accepted methodology for first establishing the fact of damage, and then further calculating aggregate damages on a class-wide basis. Plaintiffs will demonstrate, using evidence common to the Classes, that all of the VCDs sold by the Defendants during the Class Period were economically worthless. Then, using well-established data sources, as well as the Defendants' own data produced in this litigation, will show that the aggregate damages to the classes can be established on a class-wide basis.

At the class certification stage, it is sufficient that a plaintiff identify a method of measuring damages that is consistent with their theory of liability, not to actually present the damages calculations. *See Comcast Corp. v. Behrend*, 569 U.S. 26, 35 (2013). Indeed, in order to meet the predominance requirement, Plaintiffs are simply required to demonstrate that a reliable methodology exists to prove damages. *In re Suboxone (Buprenorphine Hydrochloride & Nalaxone) Antitrust Litig.*, 421 F. Supp. 3d 12, 63 (E.D. Pa. 2019), *aff'd*, 967 F.3d 264 (3d Cir. 2020). The proposed methodology must be reasonable, though it need not be perfect. *In re Modafinil*, 837 F.3d at 261 (stating that "'the damages model does not need to be exact'") (quoting *Comcast*, 569 U.S. at 37); *In re Chocolate Confectionary Antitrust Litig.*, 289 F.R.D. 200, 222 (M.D. Pa. 2012) (stating that "courts do not require [class] damages to be reduced

to a mathematical certainty"); *see also Ludlow v. BP, P.L.C.*, 800 F.3d 674, 683-685 (5th Cir. 2015) ("[A] 'sound' methodology, [is] not certainty.").

Aggregate computation of damages in class actions is well accepted by Courts. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 582 F.3d 156, 197-98 (1st Cir. 2009) (holding that "[a]ggregate computation of class monetary relief is lawful and proper. Courts have not required absolute precision as to damages…Challenges that such aggregate proof affects substantive law and otherwise violates the defendant's due process…will not withstand analysis."); *see also In re Neurontin Antitrust Litigation,* 2011 WL 286118, *10 (D.N.J. 2011) (finding aggregate damage calculation is sufficient to meet predominance requirement); *In re: Domestic Drywall Antitrust Litig.*, 322 F.R.D. 188, 234 (E.D. Pa. 2017) ("Plaintiffs must show that there is a reliable means for measuring damages with reasonable accuracy in the aggregate.") (citing cases).

Moreover, that individual calculations may be required at some later date does not defeat class certification. *In re Suboxone*, 421 F. Sup. 3d at 63; *In re Loestrin 24 Fe Antitrust Litig.*, No. 13-2472, 2019 WL 3214257, at *15 (D.R.I. July 15, 2019) ("…the individuation of damages in consumer class actions is rarely determinative under Rule 23(b)(3).") (internal quotation marks and citation omitted); *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 233 (E.D. Pa. 2012) ("Assuming the jury renders an aggregate judgment, allocation will become an intra-class matter accomplished pursuant to a court-approved plan of allocation, and such individual damages allocation issues are insufficient to defeat class certification." (internal quotation marks and citation omitted)).

a) Class Plaintiffs Establish an Ascertainable Loss Using Common Evidence

Dr. Conti first sets forth to establish an ascertainable loss attributable to the Defendants' conduct which is consistent with the Class Plaintiffs' theory of liability. Dr. Conti opines that when

the Class Members purchased generic prescription drugs (in this case, the economically worthless VCDs), they did so with the expectation that the drugs are what they are represented to be, are non-contaminated with any harmful substances, and have been produced in accordance with the cGMPs. Conti Decl. ¶¶ 4-7, 31-38. The cGMPs and applicable standards, Dr. Conti opines, are meant to assure that the drugs meet the legal requirements for safety and have the quality, purity, identity, and strength they are represented to possess. *Id*. Dr. Conti describes that these assurances to the consumers and TPPs are the "foundation upon which prescription drugs are sold and purchased in the United States. *Id.* ¶ 21. Dr. Conti goes on to describe how, from an economics perspective, drugs which are manufactured in a non-compliant manner such that a pharmaceutical manufacturer cannot assure that the drug meets the appropriate quality, purity, identity, or strength are adulterated and misbranded. *Id.* ¶¶ 21-24; *accord* Quick Decl. ¶ 105.

Dr. Conti opines that a prescription drug's availability for sale is predicated on the product having been manufactured in such a way to assure its safety and quality. Conti Decl. ¶ 44. Conversely, Dr. Conti opines that drugs which are manufactured in such a way that a manufacturer *cannot* assure their safety and quality should *not* be available for sale in the United States drug market. *Id*. Because of this, Dr. Conti finds that there is no legitimate supply curve for such drugs. *Id.* Under these circumstances, there is no equilibrium between the demand for safety and quality compliant drugs and the supply of non-compliant drugs. *Id.* Therefore, under these economic principles, there is no economically determinable price for non-compliant drugs. *Id.* Dr. Conti also opines that assigning a non-zero value to drugs which are not complaint with the standards that are required to assure their safety and quality would incentivize and legitimize the very short-cuts the Manufacturer Defendants took in manufacturing compliance. Dr. Conti concludes that "non-compliant, adulterated and misbranded prescription drugs have no economic value." *Id.* ¶ 46.

b) Class Plaintiffs Calculate Aggregate Damages to the Class Using Common Evidence

After assigning the Manufacturer Defendants' VCDs a $0 value based on their economic worthlessness, Dr. Conti then proceeds to calculate aggregate damages attributable to the various classes. Conti Decl. ¶¶ 55-79. With the exception of Wholesaler Defendants' Unjust Enrichment damages, Dr. Conti calculates these aggregate damages as the total cost paid, by either the Consumer or the TPP. Because Dr. Conti concluded that the value of the Manufacturer Defendants' VCDs was $0, the Consumer Classes and the TPP classes would be entitled to the full purchase price of their drug.

Dr. Conti calculates the aggregate damages for the Manufacturer classes using IQVIA Xponent Data. *Id.* ¶¶ 55, 71. IQVIA data is considered the gold standard for national pharmacy claims and is commonly used by industry experts and in litigation. [345] *Id* [redacted]

[345] *In re Loestrin 24 FE Antitrust Litig.,* 410 F. Supp. 3d 352, 389 (D.R.I. 2019) (writing that IQVIA data is considered "the industry standard source of pharmaceutical data used by researchers and academic.")

2. *An Inference of Reliance/Causation Is Conclusively Established Based on the Specific Facts of this Case*

The facts of this case make it particularly suitable to class certification, in part because reliance and/or causation can be proven as to all Consumer EL Class Members for both the warranty- and fraud-based claims based on common circumstantial evidence that will give rise to an inference or presumption of reliance. In circumstances where such a common-sense presumption or inference of reliance can be established as an evidentiary matter on a class-wide basis, certification has been found appropriate.

The Third Circuit has stated that a "presumption of reliance and/or causation" can be established when there is a so-called "fraud on the market" *or* when common evidence will show that all class members would have behaved similarly under the circumstances. Specifically, the Court in *Marcus v. BMW of North America, LLC,* found that such an inference is available when "(1) the alleged defects were not knowable to a significant number of potential class members … ***or*** (2) that, even if the defects were knowable, that class members were nonetheless relatively uniform in their decisionmaking …." *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 610-611 (3d Cir. 2012) (emphasis added); *see also CGC Holding Co., LLC v. Broad & Cassel*, 773 F.3d 1076, 1089-90 (10th Cir. 2014) ("Under certain circumstances, therefore, it is beneficial to permit a commonsense inference of reliance applicable to the entire class to answer a predominating question as required by Rule 23.") *Klay v. Humana, Inc.*, 382 F.3d 1241, 1259 (11th Cir. 2004) ("Consequently, while each plaintiff must prove reliance, he or she may do so through common evidence (that is, through legitimate inferences based on the nature of the alleged misrepresentations at issue"). For this reason, this is not a case in which individualized issues of reliance predominate over common questions."); *Ge Dandong v. Pinnacle Performance Ltd.*, No. 10cv086, 2013 WL 5658790, at *10 (S.D.N.Y. Oct. 17, 2013) ("That is, 'while each plaintiff must

prove reliance, he or she may do so"—in this case—"through common evidence (that is, through legitimate inferences based on the nature of the alleged misrepresentations at issue).'" (quoting *In re U.S. Foodservice Inc. Pricing Litig.*, 729 F.3d 108, 120 (2d Cir. 2013))).

In this case, consistent with the above authorities, Plaintiffs can easily establish an inference of reliance based on common circumstantial evidence. First, the presence of NDMA/NDEA in the Manufacturer Defendants' VCDs – contrary to the uniform representations by the Defendants that the drugs were valsartan or valsartan-containing, per USP/Orange Book – would not have been a fact of which any Consumer EL Class Member would have been aware or could have become aware in the exercise of reasonable diligence. It is indisputable that Class Members simply did not have access to, nor should be expected to have had access to, the fact of the contamination of the valsartan. In fact, [redacted] As Dr. Conti describes in her Declaration, the Consumer Plaintiffs were at a distinct disadvantage due to the "substantial asymmetric information about the safety and quality of prescription drugs between the manufacturers themselves" and the consumer class members.[346] Conti Decl. ¶¶ 37-39.

Further, Plaintiffs and Class Members had "no choice but to rely" on the Manufacturer Defendants' representations (and Wholesaler and Retailer Defendants' representations) that the VCDs being dispensed to them were VCDs that were generic prescription pharmaceuticals that were chemically and therapeutically equivalent to DIOVAN and/or EXFORGE. *See* MTD Op. 3,

[346] While the Manufacturer Defendants themselves may continue to desperately – and irrelevantly – claim that the presence of NDMA/NDEA was "unexpected," this is a question of fact which can be determined using common evidence. More important, it cannot be reasonably disputed that average consumers could not have known of the presence of NDMA or NDEA.

at 13-14; *see also id.* ("[a]ll they [consumers] had to know was they were buying a generic drug that contained valsartan" to have relied on Defendants' false representations giving rise to the common law fraud claims; *see also id.* (stating that the "Mfrs' identification of the drug as valsartan-containing [] informed plaintiffs the drug was approved as a generic of the Orange Book formulation, [a representation] upon which plaintiffs relied and acted on in filling their prescriptions for VCDs"); *accord* Conti Decl., ¶ 37 (opining that "patients who filled prescriptions for at-issue Valsartan products had no choice but to rely on the manufacturers' assurance[s]").) And finally, were these facts in the realm of public knowledge, it can be inferred that the FDA would have become aware almost as soon as any Class Member, which would have resulted in the much earlier withdrawal of the VCDs from the market. In other words, the NDMA/NDEA contamination of Defendants' VCDs and the inability to assure they were as represented based on egregious CGMP failures, rendered Defendants' VCDs adulterated and misbranded; therefore, it was illegal for them to have been sold, distributed, and dispensed. As these facts became known to the public, the economically worthless VCDs were withdrawn from the market. *See, e.g.*, Quick Decl. ¶ 105.

The specific facts of this case will enable Plaintiffs to establish on a classwide basis an inference of reliance that is consistent with the Court's own rulings to date. Accordingly, there are no issues regarding reliance that are sufficient to defeat predominance.

3. Materiality is Established to the Extent Any Claim Requires Such a Showing

Similarly, courts have held that the materiality of a representation, warranty, or omission can be inferred on a classwide basis when the result is an "unreasonable safety risk." *Daniel v. Ford Motor Co.*, 806 F.3d 1217, 1225-26 (9th Cir. 2015) (in the context of a fraudulent omission case, stating "[t]hat one would have behaved differently can be presumed, or at least inferred, when the omission is material … Alleged defects that create 'unreasonable safety risks' are considered

material."); *McDermott v. Cummins, Inc.*, No. 14cv4209, 2016 WL 3287335, at *6 (D.N.J. June 7, 2016) (same); *Kearney v. Bayerische Motoren Werke Aktiengesellschaft*, No. 17cv13544, 2018 WL 4144683, at *12 (D.N.J. Aug. 29, 2018) (same).

The misrepresentations and omissions herein[347] (as well as the circumstances giving rise to breach of warranty claims) created an unreasonable safety risk. The contamination of Manufacturer Defendants' VCDs with probable human carcinogens NDMA/NDEA, as well as the manufacture of Defendants' VCDs under grossly deficient cGMP conditions to the point that Manufacturer Defendants could not assure their VCDs were as they represented them to be, created an unacceptable safety risk to patients. This hardly disputed fact more than satisfies any legal requirement the consumer economic loss plaintiffs may have to meet with respect to the materiality of the misconduct, which is demonstrated by reviewing the elements of the claims at issue in this Motion (e.g., the "breach" element of warranty claims or requirements that the claimed express warranty have been a "basis of the bargain" or establishing that the defect rendered the VCDs "non-merchantable" for implied warranty purposes, or in the fraud context the "material" nature of the misrepresentation).

For express warranties, for example, the Court has already ruled in Plaintiffs' favor regarding any such materiality component:

> The issue, then, as to pleading the basis of the bargain in this situation devolves to whether plaintiffs pleaded that either individual consumers or third party payors perceived an express warranty on the VCDs at issue, and then, based on that perceived warranty, chose to buy or fund them. The Court finds that, for prescription drugs, the mere identifying and marketing a drug as THE generic equivalent to a branded pharmaceutical listed in the Orange Book and then selling that generic equivalent when it

[347] For example, as recognized in MTD Opinion 3, ZHP falsely touted its VCDs as "compliant with the current USP and Orange Book standards," meaning it was, "the therapeutic equivalent of the brand name product." *See* **Ex. 20**, Hai Wang Dep. at 82:4-85:3, 86:14-89:16.

> contains a contaminant not included in the Orange Book listing constitutes a breach of express warranty …
>
> …
>
> The Mfrs' very naming of the drug as valsartan or valsartan containing amounted to an express warranty on which plaintiffs had no choice but to "rely" when they were prescribed the drug and bought it as a medication for their high blood pressure. Plaintiffs did not have to "perceive" the package labelling or insert in order to create a benefit of the bargain. All they had to know was they were buying a generic drug that contained valsartan because the very name "valsartan" or "valsartan-containing" constituted itself an express warranty that what plaintiffs were purchasing was the chemical equivalent of the Orange Book pharmaceutical.

See MTD Op. 3, at 14 (emphasis added). The fact that the express warranties on which Plaintiffs rely conclusively formed the "basis of the bargain" for each and every Consumer EL Class Member – as this Court has determined – establishes the materiality of the assertion by definition. *See also* Conti Decl. ¶ 20 (stating that regulatory framework is directed to creating an assurance of safety).

Similarly, some fraud-based claims require that the false representations have been "material" to the transaction that caused the plaintiff's injuries and damage. For the very same reasons set forth above, and based on appellate case law, Defendants' representations that their products were valsartan or valsartan-containing, that were also chemical and therapeutic equivalents to DIOVAN and/or EXFORGE and so listed in the Orange Book, amount to materially false representations delivered to each and every consumer economic loss class member (and necessarily relied on by each and every consumer economic loss class member), that form the basis of Plaintiffs' fraud-based claims, and are susceptible to common evidence.

MTD Opinion 3 also addresses the elements of Plaintiffs' implied warranty claim, which includes an element that the VCDs were not "merchantable" at the time of sale (*i.e.*, they were

"not fit for ordinary use"). To the extent this element incorporates a "materiality" requirement, the Court found such element satisfied on the allegations in this litigation:

> This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCD's actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for. Further, contaminated drugs do create a present injury because their sale should never have occurred.

(MTD Opinion 3, at 20). The simple fact of NDMA/NDEA contamination of the VCDs is all that is required to establish their "non-merchantable" nature, and thus sustain the implied warranty claim, which seeks to only recover economic damages.

The Defendants' own statements and testimony underscore the Court's rulings on the pleadings set forth above. All Defendants have admitted that NDMA/NDEA are appropriately classified as probable human carcinogens by the International Agency for Research on Cancer ("IARC"), the National Toxicology Program ("NTP"), and the U.S. Environmental Protection Agency ("EPA") and other authorities.[348] Similarly, Defendants voluntarily recalled their respective VCDs, effectively an admission that NDMA/NDEA contaminated VCDs are non-

348 [redacted]

merchantable and unfit for ordinary use on account of the contamination.[349]

4. There Are No Uninjured Class Members Based on the Facts of the Case

Another issue common to all claims is whether there are a significant number of uninjured class members. To begin, the classes are defined to include only those Consumer EL Class Members who actually paid some amount of money out-of-pocket for the economically worthless VCDs. Any amount of money paid by Class Members in excess of $0 establishes economic injury in this case because Dr. Rena Conti, consistent with this Court's own rulings, values the VCDs as "economically worthless" as discussed *infra* at Sec. IV.F.1. (*See also* MTD Op. 3, at 20 ("This Court finds that contaminated drugs are economically worthless at the point of sale ….").)

In addition, the evidence obtained by the Plaintiffs establishes that for ZHP, Torrent, Mylan, Teva, and Hetero, during the respective class periods, *literally all* of their respective VCDs were in fact contaminated with NDMA/NDEA. Thus, there is no sub-set of Class Members for these Manufacturer Defendants who did not receive non-contaminated VCDs. Further, all Defendants during the class period(s) were manufacturing their VCDs in such a state of cGMP non-compliance that all of their VCDs were adulterated in the sense that Defendants could not assure they were as represented. *See, e.g.*, Quick Decl. ¶¶ 194-198. This resulted in their economic worthlessness. *See* Conti Decl. ¶¶ 39-46.

5. Manufacturer Express Warranty Claim: Common Questions Will Predominate Over Individual Questions Against Manufacturer Defendants

Plaintiffs seek class certification of express warranty claims against the Manufacturer Defendants on API-based FD Defendant classes set forth in the Class Definitions Table, and based on the Express Warranty State Groupings set forth in the State Groupings Table, and supported by

[349] [redacted]

the Express Warranty Legal Authorities Table.[350]

The generic elements of an express warranty claim are common across all states with certain variations discussed in more detail below. Those elements are: (1) the existence of an express warranty; (2) breach of that warranty; (3) the breach proximately caused; and (4) damages. These generic express warranty elements are all satisfied by common proof in this case.

a) The Existence of an Express Warranty Is Subject to Common Proof

To begin, Plaintiffs' express warranty claims are premised on Manufacturers' identification of their VCDs as the generic version of and chemical and therapeutic equivalent to the Orange Book/USP brand name(s) (or Reference Listed Drug(s)) – namely DIOVAN® and/or EXFORGE®– and on the Manufacturer Defendants' representations they were selling generic drugs that were valsartan or valsartan-containing. The Court has already recognized these to be express warranties made by the Manufacturer Defendants:

> In short, because of the economic reality of drug sales in the U.S., the mfr's identification of a generic drug as the chemical equivalent to the Orange Book brand name can do nothing else but constitute an express warranty … The Mfrs' very naming of the drug as valsartan or valsartan-containing amounted to an express warranty ….

(*See* D.E. 775, at 13-14 (emphasis added).)

These express warranties were indisputably made in identical fashion by each and every Manufacturer Defendant, and directed necessarily to each and every Consumer Economic Loss Class Member.[351]

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[350] **Exs. 1 & 2**.

[351] For example, Mr. Derek Glover, Mylan's Global Head of Quality, testified in a corporate designee capacity that [redacted]

b) The Manufacturer Defendants' Breaches of Express Warranties Are Subject to Common Proof

The second generic express warranty element is that the express warranty has been breached by the defendant. This is the liability component of the claim, which is clearly subject to common proof and evidence. The key facts Plaintiffs will put forth at a class trial on this point would relate to the scope of NDMA/NDEA contamination of the Manufacturers Defendants' VCDs, the exact chemical processes that occurred to create said contamination, as well as the material and substantial wrongdoing including cGMP failures of each Defendant that resulted in their inability to assure that their VCDs matched up to their labeling and were indeed "chemical equivalents" to DIOVAN and/or EXFORGE (i.e., "meets the quality and purity characteristics, which it purports or is represented to possess[,]" 21 U.S.C. § 351 (a)(2)(B)). For purposes of this Motion, Dr. Ron Najafi, opines that NDMA/NDEA-contaminated VCDs are not chemically or therapeutically equivalent to FDA-approved and/or Orange Book listed reference listed drugs. *See* Najafi Decl. at ¶¶ 32-33. All of this evidence is subject to common proof.

c) Causation and Damages

As explained *supra*, express warranty causation and damages are likewise subject to common proof and application of a class wide formula developed by Dr. Conti, and an inference of materiality is justified on a classwide basis as this Court has already found. *See* MTD Op. 3, at 13-14, 20. Dr. Conti's damages model appropriately values the VCDs as economically worthless consistent with the common evidence and this Court's legal findings. Accordingly, there are no individualized issues regarding the value to each Class Member of the VCDs; for all Class Members that value is $0.

[redacted]

d) The State Law Groupings Table Accounts for Variations in State Law Regarding Privity and Pre-Suit Notice

The Express Warranty State Groupings and Legal Authorities Tables account for state law variations with regard to privity and pre-suit notice where there is an actual conflict with regard to these facets. Citations supporting a particular state's assignment in the State Grouping Table are found within a separate Express Warranty Legal Authorities Table.[352] A few points merit further clarification and are discussed herein.

The Parties' Agreement Regarding Majority of States' Laws: As set forth in the Express Warranty Legal Authorities Table, Plaintiffs and Manufacturer Defendants have agreed in past briefing on the privity and pre-suit notice characteristics of 27 of the 51 jurisdictions[353] subject to express warranty certification in this Motion.[354]

Privity: Of the states where privity is disputed as being required or not required, Manufacturer Defendants have failed to account for judicial rulings or legislative abrogations that are clearly and indisputably applicable to the facts of this case. States subject to this express

[352] **Ex. 2**.
[353] Plaintiffs do not include Louisiana, the sole state Court dismissed by the Court with prejudice on express warranty against the Manufacturer Defendants.
[354] The "Agreed" Express Warranty jurisdictions are: Alabama, Alaska, Arizona, Arkansas, D.C., Hawaii, Idaho, Maine, Maryland, Mississippi, Montana, Nebraska, New Hampshire, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, Wyoming, and Puerto Rico.

warranty privity dispute include: Florida; [355] Georgia; [356] Illinois; [357] Indiana; [358] Iowa; [359] Kentucky;[360] Nevada;[361] and Virginia.[362] As seen in the footnoted authorities, nearly all of these states have excepted a privity requirement for express warranty claims if the express warranty is found in labeling-related materials and advertising directed to the end-user or ultimate consumer.

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[355] **Florida**: *Karhu v. Vital Pharm., Inc*., No. 13cv60768, 2013 WL 4047016, at *6 (S.D. Fla. Aug. 9, 2013) (applying Florida law to a pharmaceutical defendant and stating that "express warranties … were contained on the packaging and in the advertisements, both clearly directed toward the end-purchaser. Accordingly, based on the facts of this case, privity is not required to state a claim for breach of express warranty[.]").

[356] **Georgia**: *Terrill v. Electrolux Home Prod., Inc.*, 753 F. Supp. 2d 1272, 1288 (S.D. Ga. 2010) ("The Court therefore holds that, under Georgia law, a manufacturer who extends an express warranty to a retail buyer is in privity of contract with the buyer." (citing cases)).

[357] **Illinois**: *In re McDonald's French Fries Litig.*, 503 F. Supp. 2d 953, 957 (N.D. Ill. 2007) ("Plaintiffs argue they are exempt from alleging privity because McDonald's expressly warranted its goods to the ultimate consumers and this was the basis for the bargain and relied upon by plaintiffs … Defendant concedes this exception exists in some jurisdictions, including California and Illinois ….").

[358] **Indiana**: *Prairie Production, Inc. v. Agchem Division–Pennwalt Corp.*, 514 N.E.2d 1299 (Ind. App. 1987) (holding that where a manufacturer has made representations to a buyer in the chain of distribution in advertisements or on product labels, and the buyer relied on those representations, the buyer could assert a breach of express warranty claim notwithstanding the lack of privity between plaintiff and defendant).

[359] **Iowa**: *Des Moines Flying Serv., Inc. v. Aerial Servs. Inc.*, 880 N.W.2d 212, 222 (Iowa 2016) ("If a defective product results only in economic loss, we only allow the buyer to bring a claim under an express warranty for direct economic losses against a remote seller[.]").

[360] **Kentucky**: *Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 739-40 (W.D. Ky. 2013) ("The Court anticipates that Kentucky state courts would hold that an express warranty action can be maintained in cases such as this, where Unilever's alleged written, express warranties were clearly intended for the product's consumers.").

[361] **Nevada**: *Hiles Co. v. Johnston Pump Co. of Pasadena, Cal.,* 93 Nev. 73, 560 P.2d 154 (1977) ("Instead, we believe that lack of privity between the buyer and manufacturer does not preclude an action against the manufacturer for the recovery of economic losses caused by breach of warranties.").

[362] **Virginia**: Virginia legislatively abolished privity in express warranty actions. VA Code Ann. § 8.2-318 ("Lack of privity between plaintiff and defendant shall be no defense in any action brought against the manufacturer or seller of goods to recover damages for breach of warranty, express or implied, or for negligence, although the plaintiff did not purchase the goods from the defendant, if the plaintiff was a person whom the manufacturer or seller might reasonably have expected to use, consume, or be affected by the goods; however, this section shall not be construed to affect any litigation pending on June 29, 1962.").

This Court has previously determined that the Manufacturer Defendants' labeling (and indeed in the very naming of the VCDs valsartan or valsartan-containing) and listing in the Orange Book/USP of the VCDs as chemical equivalents to DIOVAN and/or EXFORGE constitute express warranties made to end-user consumers. *See* MTD Op. 3, at 13-14. Accordingly, under the facts of this case, these states no more require privity of contract for economic loss express warranty cases than states who legislatively abolished privity altogether. And accordingly, there is no actual conflict of law between these states where privity is so clearly excepted and states that simply do not require privity at all.

Pre-Suit Notice: Of the states where pre-suit notice is disputed as being required or not required, Manufacturer Defendants have similarly failed to account for legal rulings that make pre-suit notice effectively not required under these states' laws. States subject to this dispute include:

California; [363] Colorado; [364] Connecticut; [365] Delaware; [366] Florida; [367] Illinois; [368] Indiana; [369]

[363] **California**: *Stearns v. Select Comfort Retail Corp.*, 763 F. Supp. 2d 1128, 1142 & n.8 (N.D. Cal. 2010) ("Timely notice of breach is not required where the buyers did not purchase the product from the manufacturer directly.").

[364] **Colorado**: *Hawkinson v. A.H. Robins Co., Inc.*, 595 F.Supp.1290, 1313 (D. Colo. 1984) ("The 'seller' as the term is used in C.R.S. sec. 4-2-607(3)(a) refers to the immediate seller who delivered the goods to the buyer. Timely notice of the breach to the immediate seller is all that is required. Separate notice to the seller's supplier or the manufacturer is not necessary.").

[365] **Connecticut**: *Spencer v. Star Steel Structures, Inc.*, 900 A.2d 42, 45 (Conn. Ct. App. 2006) ("The only party entitled to notice under the statute is "the seller" of the goods.").

[366] **Delaware**: *Cline v. Prowler Indus. of Md.*, 418 A.2d 968 (Del. 1980) ("The requirement of notice has been greatly liberalized to reflect the differences between commercial buyers and consumers"); *see also* Official Cmts. 4 and 5 to Del. Code Ann. 6 § 2–607(3)(a) ("[T]he rule requiring notification is designed to defeat commercial bad faith, not to deprive a good faith consumer of his remedy ...").

[367] **Florida**: *PB Prop. Mgmt., Inc. v. Goodman Mfg. Co.*, 2014 WL 12640371, at *3–4 (M.D. Fla. Aug. 14, 2014) ("Plaintiffs are correct in their assertion that notice is required to be given to the seller, not the manufacturer, under Florida law." (emphasis in original)).

[368] **Illinois**: *In re McDonald's French Fries Litig.*, 503 F. Supp. 2d 953, 956 (N.D. Ill. 2007) ("Direct notice is not required when (1) the seller has actual knowledge of the defect of the particular product ….").

[369] **Indiana**: *In re Nexus 6P Products Liability Litigation*, 293 F.Supp.3d 888 (N.D. Cal. 2018) ("Indiana law, too, requires that the buyer give notice to the seller before bringing suit for breach of warranty. Ind. Code Ann. Sec. 26-1-2-607(3)(1). But unlike similar provisions in other states, Indiana's notification law 'is satisfied if the seller has 'actual knowledge' that the goods are nonconforming.'").

Iowa;[370] Kansas;[371] Massachusetts;[372] Minnesota;[373] Missouri;[374] New Jersey;[375] New Mexico;[376]

[370] **Iowa**: *In re MyFord Touch Consumer Litig.*, 46 F. Supp. 3d 936, 977 (N.D. Cal. 2014) ("Under Iowa law, notice to the manufacturer is not required.").

[371] **Kansas**: *Wichita v. U.S. Gypsum Co.,* 828 F.Supp. 851, 856–57 (D.Kan.1993) ("In applying the U.C.C., this court has previously held that § 84–2–607 does not require notice when the buyer is a consumer rather than a merchant."); *Carson v. Chevron Chemical Co.,* 6 Kan.App.2d 776, 785, 635 P.2d 1248, 1256, 24 A.L.R.4th 258, 269 (1981) (in ordinary buyer-seller transaction, section 2–607(3)(a) requires notice of breach only to immediate seller).

[372] **Massachusetts**; *In re Ford Motor Co. E-350 Van Prod. Liab. Litig. (No. II)*, No. CIV. A. 03-4558, 2010 WL 2813788, at *78 (D.N.J. July 9, 2010), amended, No. CIV.A. 03-4558 GEB, 2011 WL 601279 (D.N.J. Feb. 16, 2011) (finding that notice by way of "filing a complaint or joining litigation is sufficient" (citing and quoting *Delano Growers' Co-op Winery v. Supreme Wine Co.*, 473 N.E. 2d 1066, 1072 (Mass. 1985)).

[373] **Minnesota**: *Church of the Nativity v. Watpro, Inc*., 474 N.W.2d 605, 609–610 (Minn. App. 1991) (notice need go only to immediate seller and not to others in distribution chain).

[374] **Missouri**: *Ragland Mills, Inc. v. General Motors Corp.*,763 S.W.2d 357, 361 (Mo. Ct. App., 1989) (in general, buyer required to give notice of breach of warranty only to immediate seller).

[375] **New Jersey**: *Coyle v. Hornell Brewing Co.*, No. CIV.08-02797 (JBS), 2010 WL 2539386, at *6 (D.N.J. June 15, 2010) ("We agree with the reasoning in *Strzakowski* and find that notice of breach of either express or implied warranty is not required in an action against a remote manufacturer who is not the immediate seller of a product." (citing cases)).

[376] **New Mexico**: *In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Pracs. & Prod. Liab. Litig.*, 288 F. Supp. 3d 1087, 1272 (D.N.M. 2017) (The Court determines that the Supreme Court of New Mexico is likely to agree with the Supreme Court of California's reasoning that notice should not be required in these suits, because "[t]he injured consumer is seldom steeped in the business practice which justifies the rule, and at least until he has had legal advice it will not occur to him to give notice to one with whom he has had no dealings.").

Pennsylvania;[377] Rhode Island;[378] South Carolina;[379] Virginia;[380] and West Virginia.[381] As the Court will see from reviewing the cites, these states have found pre-suit notice either to be: (1) only required to an "immediate seller" (and not to a remote manufacturer, as the Manufacturer Defendants indisputably are); (2) not required when the defendant has "actual knowledge" of the defect (which is undisputed in this case since all Manufacturer Defendants recalled their VCDs prior to being named as Defendants in this litigation); and/or (3) satisfied by the filing and serving of a complaint in litigation (which again indisputably has occurred here). In other words, these states are no different from states that do not require pre-suit notice at all, based on the undisputed facts of this case.

e) Plaintiffs Have Class Representative Coverage for Each of the Express Warranty Groupings Proposed for Certification

Having established a legal basis for the Proposed Express Warranty State Groupings, Plaintiffs also have putative Economic Loss Class Representative Coverage for each of the Express Warranty State Groupings based on the Express Warranty State Groupings and Legal Authorities Tables.[382] This approach is consistent with Judge Vanaskie's well-reasoned R&R regarding the

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[377] **Pennsylvania**: *In re Nexus 6P Prod. Liab. Litig.*, 293 F. Supp. 3d 888, 914 (N.D. Cal. 2018) ("Pennsylvania state courts have held that the filing of a complaint may satisfy the notice requirement for a breach of warranty claim. *See Precision Towers, Inc. v. Nat–Com, Inc.*, No. 2143, 2002 WL 31247992, at *5 (Pa. Com. Pl. Sept. 23, 2002) ("The filing of a complaint has been held to satisfy the notice requirement for a breach of warranty claim."); *cf. Yates v. Clifford Motors, Inc.*, 283 Pa.Super. 293, 423 A.2d 1262, 1270 (1980) (holding that the filing of the complaint constituted adequate notice that the plaintiff consumer was rejecting the truck at issue).").

[378] **Rhode Island**: *DiPetrillo v. Dow Chem. Co.*, 729 A.2d 677, 683 (R.I. 1999).

[379] **South Carolina**: *Seaside Resorts Inc. v. Club Car, Inc.,* 308 S.C. 47, 416 S.E.2d 655, 663 (S.C.Ct.App.1992).

[380] **Virginia**: *Yates v. Pitman Mfg., Inc*., 257 Va. 601, 605, 514 S.E.2d 605, 607 (1999) ("We hold, therefore, that only buyers; i.e., those who buy or contract to buy goods from a seller, Code § 8.2–103(a), must give notice of breach of warranty to the seller as a prerequisite to recovery. Consequently, the trial court erred in ruling that Yates was required to have given Pitman such notice.").

[381] **West Virginia**: *Belville v. Ford Motor Co.*, 60 F. Supp. 3d 690, 702 (S.D.W. Va. 2014).

[382] **Ex. 2**.

ability of the putative Consumer EL Class Representatives to represent Class Members of other jurisdictions. (D.E. 1614, at 8-12.)

6. Manufacturer Implied Warranty Claim: Common Questions Will Predominate Over Individual Questions Against Manufacturer Defendants

Plaintiffs seek class certification of implied warranty of merchantability (hereinafter "implied warranty") claims against the Manufacturer Defendants on API-based FD Defendant classes, and based on the Implied Warranty State Groupings set forth in the Implied Warranty State Groupings and Legal Authorities Tables.[383]

The generic elements of an implied warranty claim are common across all states with certain variations discussed in more detail below. Those elements are: (1) that a merchant sold goods; (2) which were not "merchantable" at the time of sale (i.e., they were defective); (3) the plaintiff suffered injury and damages; and (4) the defect (or other condition) proximately caused the injury. *See* D.E. 775, at 18. All of these elements are subject to common proof and evidence.

a) <u>The "Sale of Goods" by the Manufacturer Defendants Is Subject to Common Proof</u>

The existence of an implied warranty of merchantability issued by the Manufacturer Defendants to Consumer EL Class Members turns simply on whether they sold the VCDs at issue; this will undoubtedly turn on common evidence. Manufacturer Defendants admit their VCDs were in fact sold, distributed, and dispensed to consumers whose ordinary use of the VCDs was to ingest them. The implied warranties of the Manufacturer Defendants were, in other words, made in identical fashion by each and every Manufacturer Defendant and occurred at the time Manufacturer Defendants placed their VCDs into the stream of commerce, and directed necessarily to each and every Consumer Economic Loss Class Member who purchased the VCDs for personal

[383] **Ex. 2**.

or household use.

To be sure, there are legal questions regarding whether a particular jurisdiction's laws allow end-users to sue remote manufacturers on a theory of implied warranty (namely, the requirement of privity); however, as discussed *infra*, Plaintiffs implied warranty state groupings take this variation into account.

b) Manufacturer Defendants' Breach of Implied Warranty and Plaintiffs' Injury is Subject to Common Evidence

A breach of the implied warranty of merchantability occurs when the goods were not "merchantable" at the time of sale (i.e., not fit for their ordinary use). Common evidence will establish that Manufacturer Defendants' contaminated, adulterated, and misbranded VCDs – which were NDMA/NDEA-contaminated and manufactured at facilities that were the subject of substantial and material cGMP violations to the point that Manufacturer Defendants could not assure their VCDs were as they represented them to be – were indeed not fit for their ordinary use (i.e., to be safely ingested as a pharmaceutical treatment for hypertension).

Indeed, this Court has already ruled that Defendants' VCDs were not "merchantable" in this case, causing Plaintiffs' economic injuries. The Court ruled as follows in discussing Plaintiffs' implied warranty claims against the Manufacturer Defendants:

> This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for. Further, contaminated drugs do create a present injury because their sale should never have occurred.
>
> Accordingly, in both the MMMC and the ELMC, individual consumer plaintiffs and third party payor plaintiffs need not demonstrate a "benefit of the bargain" theory of economic damages to plead adequately a breach of implied warranty because they have

> alleged sufficient injury and the lack of the VCDs' functionality at the motion to dismiss stage.

See D.E. 775, at 20. Further discussion on materiality is set out *supra,* at IV.F.3.

c) Consumer Economic Loss Plaintiffs' Implied Warranty Damages

As discussed below, Dr. Conti's damages model appropriately values the VCDs as "economically worthless" consistent with the common evidence, expert testimony, and this Court's legal findings that "contaminated drugs … cannot create a benefit of the bargain … individual consumer plaintiffs and third party payor plaintiffs need not demonstrate a 'benefit of the bargain' theory of economic damages to plead adequately a breach of implied warranty." (*See, e.g.,* D.E. 775, at 20; *see also* Conti Decl. ¶¶ 39-46). Accordingly, there are no individualized issues regarding the value to each Class Member of the VCDs as a result of Manufacturer Defendants' breaches of implied warranties; for all Class Members that value is $0.

d) The State Law Groupings Adequately Account for State Law Variations With Regard to Implied Warranty Claims

The Manufacturer Defendants Implied Warranty Class Definitions, State Groupings and Legal Authorities Tables[384] account for state law variations with regard to privity and pre-suit notice where there is an actual conflict with regard to these facets. Citations supporting a particular state's assignment in the State Grouping Table are found within a separate Implied Warranty Legal Authorities Table. A few points merit further clarification, and are discussed herein.

The Parties' Agreement Regarding Majority of States' Laws: As set forth in the Implied Warranty Legal Authorities Table, Plaintiffs and Manufacturer Defendants have in past briefing agreed on the privity and pre-suit notice characteristics of 32 of the 52 jurisdictions subject

[384] **Exs. 1 & 2**.

to implied warranty certification in this Motion.[385]

Privity: Of the states where privity is disputed as being required or not required, Manufacturer Defendants have failed to account for judicial rulings or legislative abrogations that are clearly and indisputably applicable to the facts of this case. States subject to this implied warranty privity dispute include: Georgia;[386] Michigan;[387] and Virginia.[388] As seen in the footnoted authorities, all of these states have excepted a privity requirement for implied warranty claims that, under the facts of this case, results in these states requiring no more privity of contract for economic loss implied warranty cases than states who legislatively abolished privity altogether. And accordingly, there is no actual conflict of law between these states where privity is so clearly excepted and states that simply do not require privity at all.

Pre-Suit Notice: Of the states where pre-suit notice is disputed as being required or not required, Manufacturer Defendants have similarly failed to account for legal rulings that make pre-

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[385] The "Agreed" Implied Warranty jurisdictions are: Alabama, Alaska, Arizona, Arkansas, D.C., Hawaii, Idaho, Illinois, Kentucky, Maine, Maryland, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, Wisconsin, Wyoming, Puerto Rico. Additionally, the claim for redhibitory defects under Louisiana law is not grouped with any other state.

[386] **Georgia**: *Terrill v. Electrolux Home Prod., Inc.*, 753 F. Supp. 2d 1272, 1288 (S.D. Ga. 2010) ("The Court therefore holds that, under Georgia law, a manufacturer who extends an express warranty to a retail buyer is in privity of contract with the buyer. Electrolux's Motion is therefore DENIED with respect to Boyd's breach of the *implied warranty* of merchantability claim." (emphasis added)).

[387] **Michigan**: *Zanger v. Gulf Stream Coach, Inc.*, No. 05-CV-72300-DT, 2005 WL 3163392, at *6 (E.D. Mich. Nov. 28, 2005) ("conclude[ing] that vertical privity no longer is required in Michigan to pursue a breach of implied warranty claim against a remote manufacturer").

[388] **Virginia**: Virginia legislatively abolished privity in implied warranty actions. VA Code Ann. § 8.2-318 ("Lack of privity between plaintiff and defendant shall be no defense in any action brought against the manufacturer or seller of goods to recover damages for breach of warranty, express or implied, or for negligence, although the plaintiff did not purchase the goods from the defendant, if the plaintiff was a person whom the manufacturer or seller might reasonably have expected to use, consume, or be affected by the goods; however, this section shall not be construed to affect any litigation pending on June 29, 1962.").

suit notice effectively not required under these states laws. States subject to this dispute include: California; [389] Colorado; [390] Connecticut; [391] Delaware; [392] Indiana; [393] Iowa; [394] Kansas; [395]

[389] **California**: *Stearns v. Select Comfort Retail Corp.*, 763 F. Supp. 2d 1128, 1142 & n.8 (N.D. Cal. 2010) ("Timely notice of breach is not required where the buyers did not purchase the product from the manufacturer directly.").

[390] **Colorado**: *Hawkinson v. A.H. Robins Co., Inc.*, 595 F.Supp.1290, 1313 (D. Colo. 1984) ("The 'seller' as the term is used in C.R.S. sec. 4-2-607(3)(a) refers to the immediate seller who delivered the goods to the buyer. Timely notice of the breach to the immediate seller is all that is required. Separate notice to the seller's supplier or the manufacturer is not necessary.").

[391] **Connecticut**: *Spencer v. Star Steel Structures, Inc.*, 900 A.2d 42, 45 (Conn. Ct. App. 2006) ("The only party entitled to notice under the statute is "the seller" of the goods.").

[392] **Delaware**: *Cline v. Prowler Indus. of Md.*, 418 A.2d 968 (Del. 1980) ("The requirement of notice has been greatly liberalized to reflect the differences between commercial buyers and consumers"); *see also* Official Cmts. 4 and 5 to Del. Code Ann. 6 § 2–607(3)(a) ("[T]he rule requiring notification is designed to defeat commercial bad faith, not to deprive a good faith consumer of his remedy ...").

[393] **Indiana**: *In re Nexus 6P Products Liability Litigation*, 293 F.Supp.3d 888 (N.D. Cal. 2018) ("Indiana law, too, requires that the buyer give notice to the seller before bringing suit for breach of warranty. Ind. Code Ann. Sec. 26-1-2-607(3)(1). But unlike similar provisions in other states, Indiana's notification law 'is satisfied if the seller has 'actual knowledge' that the goods are nonconforming.'").

[394] **Iowa**: *In re MyFord Touch Consumer Litig.*, 46 F. Supp. 3d 936, 977 (N.D. Cal. 2014) ("Under Iowa law, notice to the manufacturer is not required.").

[395] **Kansas**: *Wichita v. U.S. Gypsum Co.,* 828 F.Supp. 851, 856–57 (D.Kan.1993) ("In applying the U.C.C., this court has previously held that § 84–2–607 does not require notice when the buyer is a consumer rather than a merchant."); *Carson v. Chevron Chemical Co.,* 6 Kan.App.2d 776, 785, 635 P.2d 1248, 1256, 24 A.L.R.4th 258, 269 (1981) (in ordinary buyer-seller transaction, section 2–607(3)(a) requires notice of breach only to immediate seller).

Massachusetts;[396] Minnesota;[397] Missouri;[398] New Jersey;[399] New Mexico;[400] Pennsylvania;[401] Rhode Island;[402] South Carolina;[403] Virginia;[404] and West Virginia.[405] As the Court will see from reviewing the cites, and consistent with express warranty discussion above (the law is typically the same on pre-suit notice for implied and express warranty claims, particularly when the state has determined that it is not required), these states have found pre-suit notice either to be: (1) only

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[396] **Massachusetts**; *In re Ford Motor Co. E-350 Van Prod. Liab. Litig. (No. II)*, No. CIV. A. 03-4558, 2010 WL 2813788, at *78 (D.N.J. July 9, 2010), amended, No. CIV.A. 03-4558 GEB, 2011 WL 601279 (D.N.J. Feb. 16, 2011) (finding that notice by way of "filing a complaint or joining litigation is sufficient" (citing and quoting *Delano Growers' Co-op Winery v. Supreme Wine Co.*, 473 N.E. 2d 1066, 1072 (Mass. 1985)).

[397] **Minnesota**: *Church of the Nativity v. Watpro, Inc*., 474 N.W.2d 605, 609–610 (Minn. App. 1991) (notice need go only to immediate seller and not to others in distribution chain).

[398] **Missouri**: *Ragland Mills, Inc. v. General Motors Corp.*,763 S.W.2d 357, 361 (Mo. Ct. App., 1989) (in general, buyer required to give notice of breach of warranty only to immediate seller).

[399] **New Jersey**: *Coyle v. Hornell Brewing Co.*, No. CIV.08-02797 (JBS), 2010 WL 2539386, at *6 (D.N.J. June 15, 2010) ("We agree with the reasoning in *Strzakowski* and find that notice of breach of either express or implied warranty is not required in an action against a remote manufacturer who is not the immediate seller of a product." (citing cases)).

[400] **New Mexico**: *In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Pracs. & Prod. Liab. Litig.*, 288 F. Supp. 3d 1087, 1272 (D.N.M. 2017) (The Court determines that the Supreme Court of New Mexico is likely to agree with the Supreme Court of California's reasoning that notice should not be required in these suits, because "[t]he injured consumer is seldom steeped in the business practice which justifies the rule, and at least until he has had legal advice it will not occur to him to give notice to one with whom he has had no dealings.").

[401] **Pennsylvania**: *In re Nexus 6P Prod. Liab. Litig.*, 293 F. Supp. 3d 888, 914 (N.D. Cal. 2018) ("Pennsylvania state courts have held that the filing of a complaint may satisfy the notice requirement for a breach of warranty claim. *See Precision Towers, Inc. v. Nat–Com, Inc.*, No. 2143, 2002 WL 31247992, at *5 (Pa. Com. Pl. Sept. 23, 2002) ("The filing of a complaint has been held to satisfy the notice requirement for a breach of warranty claim."); *cf. Yates v. Clifford Motors, Inc.*, 283 Pa.Super. 293, 423 A.2d 1262, 1270 (1980) (holding that the filing of the complaint constituted adequate notice that the plaintiff consumer was rejecting the truck at issue).").

[402] **Rhode Island**: *DiPetrillo v. Dow Chem. Co.*, 729 A.2d 677, 683 (R.I. 1999).

[403] **South Carolina**: *Seaside Resorts Inc. v. Club Car, Inc.,* 308 S.C. 47, 416 S.E.2d 655, 663 (S.C.Ct.App.1992).

[404] **Virginia**: *Yates v. Pitman Mfg., Inc*., 257 Va. 601, 605, 514 S.E.2d 605, 607 (1999) ("We hold, therefore, that only buyers; i.e., those who buy or contract to buy goods from a seller, Code § 8.2–103(a), must give notice of breach of warranty to the seller as a prerequisite to recovery. Consequently, the trial court erred in ruling that Yates was required to have given Pitman such notice.").

[405] **West Virginia**: *Belville v. Ford Motor Co.*, 60 F. Supp. 3d 690, 702 (S.D.W. Va. 2014).

required to an "immediate seller" (and not to a remote manufacturer, as the Manufacturer Defendants indisputably are); (2) not required when the defendant has "actual knowledge" of the defect (which is undisputed in this case since all Manufacturer Defendants recalled their VCDs prior to be named as Defendants in this litigation); and/or (3) satisfied by the filing and serving of a complaint in litigation (which again indisputably has occurred here). In other words, these states are no different from states that do not require pre-suit notice at all, based on the undisputed facts of this case.

7. Retailer Defendant Implied Warranty Claims: Common Questions Will Predominate Over Individual Questions Against Manufacturer Defendants

For the few states where Plaintiffs continue to have implied warranty claims against the Retailer Defendants, Plaintiffs seek class certification of implied warranty of merchantability (hereinafter "implied warranty") claims against the Retailer Defendants and based on the Implied Warranty State Groupings set forth in the Retailer Defendant Implied Warranty State Groupings and Legal Authorities Tables. Plaintiffs refer the Court to the above discussion regarding the Manufacturer Defendant implied warranty claims with regard to the justifications of the state groupings.

8. Manufacturer Common Law Fraud Claims: Common Questions Will Predominate Over Individual Questions Against Manufacturer Defendants

Plaintiffs seek class certification of common law fraud claims (hereinafter "fraud") claims against the Manufacturer Defendants on API-based FD Defendant classes, and based on the Common Law Fraud State Groupings set forth in the State Groupings and Legal Authorities Tables.

The elements of a fraud claim are very consistent across jurisdictions, with the only major variation potentially worthy of creating an intra-class conflict being the scienter element; some states require only "ignorance of the truth;" some incorporate a "reckless disregard of the truth" standard; and others require "actual knowledge of the falsity" of the statement giving rise to the

alleged fraud.[406]

As the Court correctly noted, "the basic elements [of a fraud claim] are virtually the same" across all jurisdictions. *See* MTD Op. 5, at 12 (D.E. 818). The proof elements of fraud across all jurisdictions are: (1) a materially[407] false representation of fact; (2) made by the defendant; (3) with actual knowledge of its falsity (or made in reckless disregard of its truth or in ignorance of its truth); (4) on which the plaintiff placed justifiable reliance; and (5) causing injury and damages.

a) Manufacturer Defendants' Materially False Representations of Fact Were Made to All Consumers of VCDs Identically and Are Subject to Common Proof

The Court agreed with Plaintiffs' fraud theory based on false representations in the VCDs' labeling and therapeutic equivalent/Orange Book designation. Specifically, the Court wrote:

> [B]y securing FDA approval to market their generic VCDs in the United States as an Orange Book listed drug, the Manufacturing Defendants represented their VCDs were therapeutically equivalent to the reference listed drug. Similarly, by presenting consumers with an FDA approved label, the Manufacturing Defendants represented their VCDs were consistent with the safety, quality, purity, identity, and strength characteristics reflected in that label.

(MTD Op. 4, at 14.)

These representations ***by the Manufacturer Defendants*** were delivered, in identical fashion, to the entirety of the Consumer EL Class, and were necessarily "material" – as set forth *supra* at IV.F.2 & 3, to the Consumer EL Class Members' purchases of Defendants' VCDs, which they expected to be generic valsartan or valsartan-containing products as labeled and chemical and therapeutic equivalents to DIOVAN and/or EXFORGE.

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[406] Even this distinction may not be worthy of state groupings, as a jury can make factual findings with appropriate jury questionnaires. Nevertheless, Plaintiffs present such groupings as a conservative approach.

[407] Certain states do not expressly incorporate "materiality" into their elements, but nevertheless require detrimental reliance, which by definition requires the false statement to have been of a material nature.

These representations were also false, and that falsity will be proven with common evidence. Common fact evidence will show that Defendants' VCDs were contaminated with human carcinogens NDMA/NDEA, and common evidence will also establish that NDMA/NDEA-contaminated VCDs are most certainly not therapeutically or chemically equivalent to DIOVAN and EXFORGE. *See* Najafi Decl., at ¶ 33. Plaintiffs will present common evidence that Defendants' VCDs' labeling was false and misleading, evidenced by for example, FDA promulgations that NDMA/NDEA contaminated VCDs are "misbranded," which federal law defines "if [the drug's] labeling is false or misleading in any particular."[408] 21 U.S.C. § 352(a)(1). The fact that VCDs contaminated with NDMA/NDEA are "misbranded," (meaning "false or misleading in any particular") is based on evidence that is common to all Class Members and not specific to any individual's circumstances. [409]

b) <u>The *Scienter* Element is Subject to Common Proof and Plaintiffs' State Law Groupings Adequately Account for Variations</u>

The *scienter* element in a fraud case concerns itself exclusively with the defendant's knowledge regarding the falsity of its statements that the plaintiff alleges were materially false. Issues regarding the defendant's level of knowledge to meet the applicable *scienter* requirement are necessarily issues that are common to the class. For example, common evidence will establish that the ZHP Defendants had "actual knowledge" of NDMA contamination in their VCDs long before the mid-2018 recall.[410] Common evidence will also establish that other Manufacturer Defendants delayed their recalls to continue selling what they knew or suspected were

[408] **Ex. 190,** Pl-Glover-74; **Ex. 191**, Pl-Glover-75 ([redacted]).
[409] *See* Quick Decl. ¶¶103-186, 191.
[410] **Ex. 32**, Min Li Dep. Tr. 82:14-90:2, 92:11-20.

contaminated VCDs. The acquisition of actual knowledge by the Manufacturer Defendants affects all consumers of their VCDs equally and there are no individual circumstances of class members that would be subject to different qualitative proof when this element of the fraud claim concerns itself exclusively with the Manufacturer Defendants' knowledge. The same is true for establishing *scienter* through recklessness. Plaintiffs will put forth evidence that the Manufacturer Defendants' substantial and material cGMP violations meant that they could not assure that their VCDs were as they represented them to be, and when the Manufacturer Defendants' labeled and sold them as valsartan prescription drugs, listed in Orange Book/USP as chemically and therapeutically equivalent to DIOVAN and EXFORGE, those statements were made in reckless disregard of whether they were true statements. Issues regarding cGMP compliance and regulatory compliance generally are common issues subject to class-wide proof, and there are no individual circumstances of class members that affect this inquiry. *See* Quick Decl. ¶¶ 37-75, 103-186, 191

In addition, Plaintiffs' Common Law Fraud Class Definitions, Manufacturer State Groupings, and Legal Authorities Tables[411] accounts for states' different levels of proof regarding *scienter*. As explained briefly above, the 52 jurisdictions (including D.C. and Puerto Rico) employ three (3) different standards for *scienter*: (1) ignorance of truth; (2) reckless disregard of truth; or (3) actual knowledge of the falsity of the statements.

The Parties' Agreement Regarding Majority of States' Laws: As set forth in the Common Law Fraud Legal Authorities Table, Plaintiffs and Manufacturer Defendants agree on the *scienter* designation of 42 of the 52 jurisdictions.[412]

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[411] **Exs. 1 & 2**.

[412] The "Agreed" Common Law Fraud jurisdictions are: Alabama, Colorado, Delaware, D.C., Florida, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey,

Plaintiffs' Legal Authorities Where There Is Disagreement: As far as the "Disagreed" jurisdictions, Plaintiffs provide directly on point citations to support their position: Alaska;[413] Arizona;[414] Arkansas;[415] California;[416] Connecticut;[417] Georgia;[418] Hawaii;[419] Illinois;[420] Massachusetts;[421] Pennsylvania.[422]

New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, and Puerto Rico.

[413] **Alaska**: *Zeman v. Lufthansa German Airlines*, 699 P.2d 1274, 1285 (Alaska 1985); *see also Larson v. Hugill*, 15 Alaska 348, 356 (D. Alaska 1954) ("To make out a case of fraud the party must prove every element necessary to constitute such, including knowledge of falsity or reckless disregard for truth, intent to deceive, reliance upon such representations, the materiality thereof and damage resulting therefrom, which must concur with the fraud.").

[414] **Arizona**: *Marcus v. Fox,* 150 Ariz. 342, 344, 723 P.2d 691, 693 (App.1985), *vacated in part by* 150 Ariz. 333, 723 P.2d 682 (1986); *Comerica Bank v. Mahmoodi,* 224 Ariz. 289, 291–92, 229 P.3d 1031, 1033–34 (Ct. App. 2010).

[415] **Arkansas**: *Jewell v. Fletcher,* 2010 Ark. 195, 377 S.W.3d 176; *Muccio v. Hunt,* 2016 Ark. 178, 4–5, 490 S.W.3d 310, 312–13 (2016).

[416] **California**: *Graham v. Bank of Am., N.A.*, 226 Cal. App. 4th 594, 605-06 (2014) (internal quotation marks and citation omitted).

[417] **Connecticut**: *Tuzinkiewicz v. Steckel*, No. FSTCV126016035S, 2013 WL 1849279, at *2 (Conn. Super. Ct. Apr. 10, 2013) ("The elements of common-law fraud include the possibility that the false representation was made recklessly, therefore counts two and three may be considered together.").

[418] **Georgia**: *Abrams & Wofsy v. Renaissance Inv. Corp.,* 820 F. Supp. 1519, 1530 (N.D. Ga. 1993) ("Under Georgia law, the scienter requirement encompasses either actual knowledge or recklessness." (citing *American Viking Contractors, Inc. v. Scribner Equip. Co., Inc.*, 745 F.2d 1365, 1372 (11th Cir.1984), *Grizzle v. Guarantee Ins. Co.*, 602 F.Supp. 465, 467 (N.D. Ga.1984) and *Irvin v. Lowe's of Gainesville, Inc.*, 165 Ga. App. 828, 830, 302 S.E.2d 734 (1983))).

[419] **Hawaii**: *Miyashiro v. Roehrig, Roehrig, Wilson & Hara*, 122 Haw. 461, 482–83, 228 P.3d 341, 362–63 (Ct. App. 2010) (scienter element stated as "with knowledge of their falsity (*or without knowledge of their truth or falsity*)" (emphasis added)).

[420] **Illinois**: *Duran v. Leslie Oldsmobile, Inc.*, 229 Ill.App.3d 1032, 1039, 171 Ill.Dec. 835, 594 N.E.2d 1355 (1992) (scienter element "that was known or believed by the speaker to be untrue *or made in culpable ignorance of its truth or falsity*" (emphasis added)).

[421] **Massachusetts**: *Welch v. Barach*, 84 Mass. App. Ct. 113, 120, n.11, 993 N.E.2d 742, 748 (2013) ("In Massachusetts, the prima facie elements of intentional misrepresentation (or "deceit") are (a) an intentional or reckless (b) misstatement (c) of an existing fact (d) of a material nature, (e) causing intended reasonable reliance and (f) financial harm to the plaintiff.").

[422] **Pennsylvania**: *Gruenwald v. Advanced Computer,* 730 A.2d 1004, 1014 (Pa.Super.1999) (scienter element as "made falsely, with knowledge of its falsity or recklessness as to whether it is true or false").

c) Consumer Economic Loss Plaintiffs' Reliance Is Conclusively Established in this Case as to All Class Members

As discussed *supra* at IV.F.2 & 3, reliance and materiality are subject to a classwide inference based on common evidence.

9. Consumer Protection Act Claims: Common Questions Will Predominate Over Individual Questions Against Manufacturer, Wholesaler, and Retailer Defendants

Plaintiffs seek class certification of consumer protection act claims (hereinafter "Consumer Protection Claims") claims against the Manufacturer Defendants based on API-based FD Defendant Class Definitions, and based on the Consumer Protection Claims State Groupings set forth in the State Groupings and Legal Authorities Tables.[423]

As a general matter, "[c]laims arising under consumer protection statutes are well-suited for class certification." *Tait v. BSH Home Appliances Corp.*, 289 F.R.D. 466, 474 (C.D. Cal. 2012) (citing *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997)). And indeed, courts have found that consumer protection act claims can be subject to multi-state certification because the states' laws are sufficiently similar. *In re Pharmaceutical Average Wholesale Price Litig.*, 252 F.R.D. 83, 93-94 (D. Mass. 2008) (certifying multi-state classes of consumer protection act claims based on similarity of state laws).

a) Most States' Consumer Protection Act Claims Contain Similar Substantive Language Regarding Violations

As the Court can see from the Consumer Protection Legal Authorities Table, many states contain very similar (if not identical) language setting forth substantive violations. This is no mere coincidence. The great majority of states passed their respective consumer protection acts either based on the Uniform Deceptive Trade Practices Act or the Uniform Consumer Sales Practices Act in the 1960s and 1970s.

[423] **Exs. 1 & 2**.

As one concrete example, Plaintiffs contend that Manufacturer Defendants misrepresented the FDA's "approval" and/or the Orange Book "certification" of the VCDs. A full twenty-five (25) of the jurisdictions define a statutory violation as including deceptive practices relating to "the source, sponsorship, approval, or certification of goods[.]"[424] The remaining jurisdictions that that do not contain this specific violation language supply similarly worded broad prohibitions that make "deceptive" or "unfair" acts or practices violations.[425]

In other words, the substantive language of these statutes is – if not identical – similar enough to support state groupings particularly on the specific facts of this case.

b) Most States' Interpretation of their Laws Are Based on the FTC Act

Defendants may contend that even if the language of the consumer protection acts are substantially the same, that identity of statutory language does not guarantee that these states apply similar interpretations pursuant to case law.

First, the Court should not credit legal arguments based on hypothetical judicial decisions that do not exist. There is simply no case where a state court, interpreting its consumer protection act, has found that a Manufacturer Defendant holding out its products as FDA-approved, when in fact they were contaminated with unlabeled substances injurious to human health, has not violated state statute.[426]

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[424] These jurisdictions include: Alabama, Alaska, Arkansas, California, Colorado, D.C., Georgia, Idaho, Indiana, Kansas, Maryland, Michigan, Nevada, New Hampshire, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Utah, Virginia, West Virginia, and Wyoming. (*See generally* Consumer Protection Claims Legal Authorities Table.)

[425] These jurisdictions include: Arizona; California's UCL § 17200; Connecticut; Delaware; Florida; Hawaii; Illinois; Iowa; Kentucky; Louisiana; Maine; Massachusetts; Minnesota; Missouri; Montana; Nebraska; New Jersey; New Mexico; New York; North Carolina; North Dakota; Puerto Rico; South Carolina; South Dakota; Vermont; and Washington.

[426] Plaintiffs note the anomaly of Michigan, which has held that "authorized transactions" are "exempt" from the statute's scope even if otherwise sufficient to state a violation. In *In re Nat'l Prescriptions Opiate Litig.*, a federal district court found this exemption applied to

Second, most states do interpret their consumer protection act statutes based on similar guidance. Out of the fifty-two (52) jurisdictions at issue here, a full twenty-nine (29) jurisdictions explicitly provide that courts should defer and/or look to the FTC Act and interpretations thereof for guidance on interpreting the substantive scope of their own consumer protection act statutes.[427] At least one court has found that these FTC-guided states are similar enough to be subject to multi-state groupings. *In re Pharmaceutical Average Wholesale Price Litig.*, 252 F.R.D. at 93-94. The "FTC Policy Statement on Deception" in 1983 sets forth the FTC's interpretation of "deception," which is still in effect to this day.[428] That Policy Statement states as follows in relevant part:

> Certain elements undergird all deception cases … Practices that have been found misleading or deceptive in specific cases include false oral or written representations … sales of hazardous or systematically defective products or services without adequate disclosures … and failure to meet warranty obligations.

Ex. 192, (FTC Policy Statement, at 1).

The Manufacturer Defendants' conduct unquestionably fits within, at minimum, those examples of deception provided by the FTC. The Manufacturer Defendants falsely represented that their VCDs were valsartan or valsartan-containing prescription drugs as approved, and

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pharmaceuticals. 458 F. Supp. 3d 665, 690 (N.D. Oh. 2020). However, that case is distinguishable because there was no contention that the opioids were not sold as approved by the FDA, but rather the claims related to their marketing. Here, Plaintiffs contend that the sale of the VCDs occurred without FDA approval, and thus the "authorized transaction" exemption would not apply. Nevertheless, Plaintiffs have omitted Michigan and Rhode Island (also with a broad exemption along these lines) from their Consumer Protection Claims State Groupings in an abundance of caution.

[427] These states include: Alabama; Alaska; Arizona; Connecticut; D.C.; Florida; Georgia; Hawaii; Idaho; Illinois; Louisiana; Maine; Maryland; Massachusetts; Mississippi; Montana; New Hampshire; New Mexico; North Carolina; Ohio; Puerto Rico; Rhode Island; South Carolina; Tennessee; Texas; Utah; Vermont; Washington; and West Virginia. (*See* Consumer Protection Claims Legal Authorities Table.)

[428] *See* https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority (last visited Nov. 2, 2021) (linking to the 1983 "Policy Statement on Deception")

certified Orange Book/USP therapeutic and/or chemical equivalents to DIOVAN and/or EXFORGE; the Manufacturer Defendants' VCDs were hazardous and systematically defective without adequate disclosures; and the Manufacturer Defendants failed to meet express and implied warranty obligations, as this Court has already determined. *See* MTD Op. 3, at 13-14, 20. This Court can very well assume, then, that all states that look to the FTC Act for guidance would therefore conclude as much with respect to applying the common evidence on liability to their consumer protection act statutes. Even for those states that do not explicitly refer to the FTC for guidance, it is quite clear that the Manufacturer Defendants' alleged deceptive acts and practices fit within the meaning of their respective statute(s).

Ultimately, to be grouped, state laws do not have to be identical; they merely need be similar enough such that common issues predominate over individual ones and no present and fundamental intra-class conflicts arise. The substantive scope of the law of the jurisdictions subject to the Consumer Protection Claims Class Definitions and State Groupings Tables are similar enough to satisfy these requirements. *In re Average Wholesale Price Litig.*, 252 F.R.D. at 93 ("Differences among applicable state laws are not necessarily fatal to certification of a proposed class action."); *see also Klay v. Humana, Inc.*, 382 F.3d 1241, 1262 (11th Cir. 2004) ("[I]f a claim is based on a principle of law that is uniform among the states, class certification is a real possibility.").

c) <u>The Consumer Protection Claims State Groupings Account for Varying Levels of Intent</u>

One area where these jurisdictions' interpretation of their respective consumer protection acts differs is the level of *scienter* required to establish a violation. Plaintiffs' Consumer Protection

Claims State Groupings and Legal Authorities Tables account for this variable,[429] and support for each jurisdiction's position is documented in the Consumer Protection Claims Legal Authorities Table.

As the Court will see, most states dispensed with the requirement that defendants have intent or knowledge, in part taking their cues from the FTC Act interpretation which also does not require intent. *See Beneficial Corp. v. F.T.C.*, 542 F.2d 611, 617 (3d Cir. 1976) ("An intent to deceive is not an element of a deceptive advertising charge under s 5."). Rather, the focus of these states is on whether the alleged deception had the ability to mislead a reasonable consumer (*see, e.g.*, Maryland in the Consumer Protection Claims Legal Authorities Table). As this Court has found, the acts giving rise to the "deception" are common facts, which this Court has already determined are sufficient to support fraud-based causes of action. (MTD Op. 4, at 16 (stating with respect to fraud-based claims that "so have Plaintiffs here set forth a litany of allegations showing how of each of the Manufacturing Defendants violated cGMPs and then disregarded significant indications of contamination after violating good manufacturing practices. In other words, plaintiffs have alleged a sequence of cause and effect that defendants, had they been even marginally diligent and/or forthright, should have and would have noticed and responded to.").) The "litany of allegations" in support of fraud-based claims are now presented as a "litany of facts" established by discovery as to each Manufacturer Defendant, *supra*.

Equally, common issues will predominate from the Class Members' perspective on the capacity to deceive, which is an objective standard under all jurisdictions' laws. Even if some state laws were to take a subjective view of deception (i.e., was the consumer actually deceived by the

[429] As set forth above with respect to fraud claims, Plaintiffs believe that differences regarding *scienter* do not necessarily require grouping as a jury can handle such determinations through jury questionnaires. Nevertheless, Plaintiffs take a conservative approach.

alleged deception), the answer on these facts is invariably and indisputably yes as to all Consumer Economic Loss Class Members. The Manufacturer Defendants themselves have claimed in public statements and otherwise that the contamination was "unexpected" even for sophisticated pharmaceutical manufacturers (a characterization Plaintiffs vehemently dispute); they cannot credibly claim at the same time that consumers should have been on alert as to the possibility of NDMA/NDEA in their VCDs. And, as explained by Dr. Conti, all Consumer Economic Loss Class Members will be in the same position regarding their lack of and inability on their own to obtain knowledge of the contamination of their VCDs due to the asymmetrical nature of the information and knowledge. Conti Decl. at ¶¶ 37-39.

d) Reliance is Established as a Matter of Law

Some state laws require that the plaintiff have relied on the deception. However, as set forth above, Plaintiffs intend to establish a classwide inference as to reliance based on common evidence, supported by applicable case law on that point as well as this Court's rulings. (*See* MTD Op. 3, at 13-14, 20 & MTD Op. 4, at 12-18.)

e) State Law Differences in Remedies and Associated Fact Determinations Can Be Addressed Via Jury Instructions and Questionnaires

Some state Consumer Protection Claims feature provisions that unlock additional remedies (e.g., trebling of damages or civil penalties) if certain facts are found. In nearly all of these jurisdictions, the statute provides the Court with discretion in awarding such amounts predicated on the trier of fact's factual findings at trial. For example, some states that do not require intent nevertheless authorize civil penalties if the defendant's violations were indeed accomplished knowingly.

These scenarios can easily be handled via jury questions as set forth in the proposed Trial Plan (**Ex. 193**) and do not impact the ability of the Court to group these states together.

Furthermore, Dr. Conti's damages model contains state-specific aggregate damages as well as numbers of prescriptions, and therefore the Court can easily apportion additional damages and/or civil penalties based on available state-specific information that will be presented at a class trial.

f) Public Interest Element

Some state consumer protection claims require that the plaintiff establish that the case affect the public interest. As with reliance and materiality, to the extent any state does require proof on this point, such proof is amenable to a classwide inference based on common evidence. Indeed, the Court itself made the following observation:

> There is tremendous public interest in this case. It has enormous public health consequences -- whether a very popular drug supplied in the United States was contaminated or not.

(12/18/19 CMC Tr., at 24:1-4.)

It is beyond dispute that this litigation, which directly affects millions of Americans as putative Consumer Economic Loss Class Members, also serves a broader public interest by seeking to hold the generic pharmaceutical industry to its promises and representations regarding their prescription drug products.

g) Actual Damages and Statutory Damages/Penalties Are Subject to Common Evidence

As discussed in more detail *infra*, Plaintiffs' actual and/or statutory damages/penalties are susceptible to common evidence, and through the use of detailed jury questionnaires where predicate factual findings can unlock additional forms of relief. Furthermore, Dr. Conti can supply the Court and the jury with sufficient state-specific information to allow the state-specific apportionment of additional damages and/or civil penalties where available.

10. Wholesaler and Retailer Unjust Enrichment Claims: Common Questions Will Predominate Over Individual Ones

Plaintiffs assert unjust enrichment claims against the Wholesaler Defendants and the Retail Pharmacy Defendants, who retained the benefit of selling and profiting from the sale of VCDs to Consumer Economic Loss Class Members. The elements of a traditional unjust enrichment claim, as this Court noted, include: (1) the conferral of a benefit on the defendant by the plaintiff; (2) appreciation and knowledge of the benefit by the defendant; (3) the acceptance of the benefit by the defendant under inequitable circumstances. *See* MTD Op. 6, at 26 (D.E. 1019).

All of these elements are subject to common classwide proof as to both the Wholesaler Defendants and Retailer Defendants. As to the first element, all Consumer Economic Loss Class Members conferred benefits upon both the Wholesalers and Retailer Defendants under common circumstances (*i.e.,* they paid Retailer Defendants for VCDs that were supplied by the Wholesaler Defendants). As to the second element, the focus is on the Wholesaler or Retail Pharmacy's appreciation and knowledge of the benefit; elements of claims focused on a defendant's state of mind or conduct are inherently susceptible to common classwide proof. Finally, given that the transactions are all susceptible to common proof; the element of whether such transactions were inequitable so as to warrant restitution will necessarily turn on common questions of fact and law.

Accordingly, the only obstacle to class certification here is the propriety of Plaintiffs' multi-state groupings as set forth in the Unjust Enrichment Class Definitions, State Groupings and Legal Authorities Tables.[430]

a) **The Wholesaler and Retailer Defendant State Groupings Table Accounts for State Law Differences in the Level of "Unjust" Conduct Required of the Defendant**

Somewhat analogous to *scienter* in the context of fraud-based claims, some states require

[430] **Exs. 1 & 2**.

that the unjust enrichment defendant himself maintain a level of culpability to be held accountable on a theory of unjust enrichment. Plaintiffs' Unjust Enrichment State Groupings Table accounts for these differences by appropriate and thorough case law evaluation. The Wholesaler Defendants, in particular, submitted legal authorities on this point in the Motion to Dismiss briefing that presents incorrect assertions regarding a number of states law (i.e., exaggerating greatly the number of states that require some level of wrongdoing on the part of the defendant). *See* D.E. 522-2. As a couple clear examples, the Wholesaler Defendants assert that wrongful conduct on the part of the defendant is required in California, Florida, and Oregon, although the cases they cite as support all provide explicitly that unjust enrichment is available when the defendant was unjustly enriched through "mistake[,]" which by definition applies in situations where no party is at fault.

b) <u>The Wholesaler and Retailer Unjust Enrichment State Groupings Account for State Law Differences in Whether Unjust Enrichment is Available Only as an Alternative Form of Relief</u>

The Unjust Enrichment State Groupings Tables also account for differences in whether the claim is available alongside other claims at law, or is only available as an alternative form of relief. As it happens, the parties agree on the vast majority of jurisdictions' laws in this regard, with disagreement only in the following jurisdictions: Arizona;[431] and Connecticut.[432]

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[431] **<u>Arizona</u>:** MTD Op. 6, at 29 & n.30 (D.E. 1019): "The Court has reviewed each of the cases cited in footnote 29 and finds the cases cited under Arizona law and North Dakota law do not support the proposition that a plaintiff must plead there is no adequate remedy in the law for the unjust enrichment claims and discusses its disagreement in footnote 30."; *see also Isofoton, S.A. v. Giremberk*, No. CV–04–0798–PHX–ROS, 2006 WL 1516026, at *3 (D.Ariz. May 30, 2006) ("An unjust enrichment count should not be dismissed unless it [is] insufficient apart from its inconsistency with the other counts.").

[432] **<u>Connecticut</u>**: *Dicin Elec. Co., Inc. v. O & G Indus., Inc.*, No. HHDCV166070813S, 2017 WL 2764752, at *2 (Conn. Super. Ct. May 25, 2017) (argument that absence of adequate remedy at law was required was "incorrect").

c) The Wholesaler and Retailer Unjust Enrichment State Groupings Account for State Law Differences Regarding Whether the Benefits Have Been Directly Provided by the Plaintiff to the Defendant

Some states require that a direct benefit had been provided by the plaintiff to the defendant as a condition of an unjust enrichment claim. As with the other unjust enrichment state law differences, Plaintiffs' Unjust Enrichment State Groupings Table accounts adequately for these state law differences. Plaintiffs and Defendants appear to only disagree on two of the jurisdictions: Alabama;[433] and New York.[434]

d) Unjust Enrichment Damages Against Wholesaler and Retail Pharmacy Defendants are Subject to Common Classwide Proof

As with Plaintiffs' warranty, fraud and consumer protection claims, damages attributable to unjust enrichment claims can be demonstrated with common proof.

Indeed, in her declaration, Dr. Conti provides a methodology for calculating the unjust enrichment damages associated with the Retail Pharmacy Defendants (*see* Conti Decl. ¶¶ 63-67) as well as the Wholesaler Defendants (*see* Conti Decl. ¶¶ 80-86). This theory is specifically tethered to Plaintiffs' theories of liability. *See Neale v. Volvo Cars of N. Am, LLC*, 794 F.3d 353, 374-75 (3d Cir. 2015) (limiting reach of *Comcast Corp. v. Behrand*, 133 S. Ct. 1426 (2013)).

Dr. Conti's model correctly attributes the distinctions between the Retail Pharmacy Defendants and the Wholesalers in terms of their relationship with the Class Plaintiffs, and their overall role in the larger drug distribution chain. *See* Conti Decl. at ¶¶ 47-54. She then incorporates these distinctions in order to create a methodology for determining how to go about calculating damages attributable to each defendant. *See* Conti Decl. at ¶¶ 55-86.

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[433] **Alabama**: *Abernathy v. Church of God*, No. 4:11-CV-2761-VEH, 2011 WL 13135285, at *2 (N.D. Ala. Nov. 28, 2011) (stating that "any notion that *Hancock-Hazlett* requires proof of a direct benefit in order to sustain an unjust enrichment claim under Alabama law is misplaced at best").
[434] **New York**: *Hughes v. Ester C Co.*, 930 F. Supp. 2d 439, 471 (E.D.N.Y. 2013) ("Under New York law, unjust enrichment does not require a direct relationship between the parties.").

For the Retailers, because they receive money at the point of sale, Dr. Conti calculates damages accounting for the amounts gained by the Retail Pharmacy Defendants from the Consumer Class Plaintiffs at point of sale, and accounts for pertinent potential deductions (such as dispensing fees). Conti Decl. at ¶ 78.

For the Wholesalers, because they are intermediaries who distribute the products, Dr. Conti has developed a flexible formula focused on the amounts gains by the Wholesalers on their sales of VCDs, which can accommodate the factual or legal findings of the jury. Conti Decl., at ¶¶ 80-86. This formula accounts for the costs associated with the Wholesalers distribution activities, as well as any other deductions, reimbursements or the like, which might impact the Wholesaler Defendants' overall profits. While Dr. Conti does not provide the actual calculations to show the amount attributable to each class member as a result of each Wholesaler Defendant's conduct (in part because the Court deferred discovery from Wholesalers on certain metrics, e.g., Wholesalers' costs), it is sufficient to provide an aggregate damages model at this time, subject to potential offsets that Wholesalers might argue at a later time (which themselves constitute common evidence). *See, e.g.*, *In re Suboxone (Buprenophrine Hydrochlorine & Naxolene) Antitrust Litig.*, 967 F.3d 264, 271-72 (3d Cir. 2020); *see also, e.g.*, *Rikos v. Procter & Gamble Co.*, 799 F.3d 497 (6th Cir. 2015) (certifying multi-state class of consumers who purchased subpar probiotic nutritional supplements); *In re TD Bank, N.A. Debit Card Overdraft Litig.*, 325 F.R.D. 136, 174 (D.S.C. 2018) (certifying three unjust enrichment subclasses); *In re Checking Account Overdraft Litig.*, 286 F.R.D. 645 (S.D. Fla. 2012) (certifying multi-state unjust enrichment classes).

G. A Class Action is Superior to Other Methods of Adjudication and Will Be Manageable

In considering "superiority" under Rule 23(b)(3), courts analyze: (i) class members' interest in individually controlling their separate actions; (ii) the extent and nature of existing

litigation by class members concerning the same claims; (iii) the desirability of concentrating the litigation in a particular forum; and (iv) the likely difficulties of managing a class action. *See* Fed. R. Civ. P. 23(b)(3)(A)-(D). The superiority analysis places "great weight on whether the individual members can bring their own claims" and alternative forms that class members' claims can be resolved. *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 533–34 (3d Cir. 2004) ("The superiority requirement 'asks the court to balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication.'" (quoting *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 316 (3d Cir. 1998))). All four factors weigh in favor of certification here.

On the first factor, the class members here have little if any interest in controlling the prosecution of separate actions. Individual class members' claims "are likely to be relatively small such that any one class member would have little interest in prosecuting the case." *Sourovelis v. City of Phila.*, 515 F. Supp. 3d 321, 335-36 (E.D. Pa. 2021); *see In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d at 534 (finding superiority element met where "each consumer has a very small claim in relation to the cost of prosecuting a lawsuit. Thus, from the consumers' standpoint, a class action facilitates spreading of the litigation costs among the numerous injured parties and encourages private enforcement of the statutes."). The identity of claims also suggests "no individual class member has an interest in controlling the prosecution." *Heinz v. Dubell Lumber Co.*, No. 19-8778, 2020 WL 6938351, at *8 (D.N.J. Nov. 25, 2020) (Kugler, J.) (granting motion to certify class).

On the second factor, Plaintiffs are unaware of any other class actions against Defendants regarding the issues raised in this case, and given the MDL status such actions would be centralized before this Court.

On the third factor, it would be far more efficient for the Court and the parties to have a single coordinated adjudication, rather than multiple separate cases about the same issues. *Heinz*, 2020 WL 6938351, at *8. There are hundreds of thousands (or more likely, millions) of Consumer EL Class Members here. *See* Craft Decl. ¶ 52, Table 7. Declining to certify the class may result in many thousands of separate actions "on essentially the same facts with inconsistent outcomes or, perhaps, far more likely, many of the claims not being brought" at all. *Id.*; *see, e.g., Bing Li v. Aeterna Zentaris, Inc.*, 324 F.R.D. 331, 345-46 (D.N.J. 2018). By contrast, concentration of the claims in a class action "would be an efficient use of limited judicial resources." *Utesch v. Lannett Co., Inc.*, No. 16-5932, 2021 WL 3560949, at *10 (E.D. Pa. Aug. 12, 2021).

Finally, on the fourth factor, a class trial on the single cause of action in this case will not present any significant manageability issues, if any at all. Defendants' illegal conduct occurred in affected Class Members nationwide and the trial will focus on same. Both liability and damages are subject to common proof on all the claims subject to proposed class treatment in this Motion, as discussed above. Consistent with Rule 23(b)(3), certification of this action as a class action would not only be superior to other methods, but it is for all practical purposes the *only* method for fairly and efficiently litigating the claims of all members of the proposed class. *See, e.g.*, *Utesch*, 2021 WL 3560949, at *10 (class treatment presented no overwhelming manageability problems because "common questions of law and fact are central to each class member's claim"); *Heinz*, 2020 WL 6938351, at *8 (class treatment presented no perceived difficulty because class sought monetary relief "which should easily be computed"). Plaintiffs' Proposed Trial Plan further illustrates how there are no intractable manageability issues. **Ex. 193**, (Plaintiffs' Proposed Trial Plan).

H. Class Notice Should Be Disseminated By a Court-Approved Administrator.

Class notice should be disseminated following the certification of the Class, pursuant to Fed. R. Civ. P. 23(c)(2)(B). Plaintiffs propose that the Court enter a separate order regarding notice, following a ruling on class certification. Plaintiffs propose that notice be disseminated by an appropriate Notice Administrator, subject to Court approval and Plaintiffs will present the Court with a notice plan within ten (10) days of any favorable ruling on class certification.

V. CONCLUSION

Plaintiffs respectfully request that the Court: (a) certify the Classes pursuant to Fed. R. Civ. P. 23(a) and (b)(3) cited in **Ex. 1**; (b) appoint Ruben Honik, Conlee S. Whiteley, and John R. Davis as Class Counsel pursuant to Fed. R. Civ. P. 23(g); and (c) appoint the Named Plaintiffs as the Consumer EL Class Representatives as found in **Ex. 1** to serve as class representatives.

Dated: November 10, 2021

Respectfully submitted,

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MDL Plaintiffs' Co-Lead Counsel

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of November, 2021, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ David J. Stanoch
David J. Stanoch